

EFFECT OF A HEART BEATING BREATHING DOLL ON INFANT SLEEP

A thesis in partial fulfilment of the requirement for the Degree of
Master of Arts in Child and Family Psychology

Hannah O'Loughlin
University of Canterbury
2018

Supervisors:
Associate Professor Karyn France
Dr Laurie McLay

Table of Contents

Abstract.....	2
Chapter One	3
Introduction and Literature Review	3
Sleep Research Methodology	7
Polysomnography.	8
Videosomnography.	8
Direct behavioural observations.	8
Sleep diaries.	9
Actigraphy.....	9
Development of Sleep.....	10
Longest sleep period.	11
Longest self-regulated sleep period.	11
Sleeping through the night.	12
Night wakings.	13
Sleep Wake States	15
Awake/Wakefulness.	15
Out of crib time (OOC).....	16
Active and quiet sleep.	16
Factors that Influence Sleep Development in Infancy.....	17
Biological Influences.	18
Circadian Rhythm and Entrainment.....	18
Infant Temperament.....	19

Environmental Influences.	22
Caregiving behaviour.....	23
Effect of removing parental intervention.....	24
Parental cognitions and beliefs.	26
Parental tolerance to crying	27
Kangaroo Care Research.	28
Kangaroo care and sleep with premature infants.....	29
Kangaroo care and sleep with full term infants.	31
Environmental Noise and Sleep.....	32
Heartbeat sound and sleep.	32
White noise and sleep.	36
Breathing Bear Research	38
Breathing bear and sleep.....	38
Breathing bear research and infant crying.	39
Aims of the Study	41
Chapter Two.....	42
Method	42
Participants and Recruitment.....	42
Ethics.....	44
Settings	44
Apparatus	45
Camera.	45
Lulla Doll.....	45
Measures	45
Videosomnography	45

Parent report sleep diaries.....	48
Interviews.....	49
Design	50
Procedure.....	50
Baseline.....	50
Intervention.....	51
Follow up.....	51
Data Analysis.....	51
Reliability.....	52
Videosomnography.....	52
Sleep Diaries.....	52
Chapter Three	53
Results	53
Quality of data.....	53
Kelly.....	53
Matt.....	53
Beth.....	53
Char.....	53
Follow up 1.....	54
Behavioural intervention.....	54
Follow up 2.....	54
Oliver.....	54
Behavioural intervention.....	55
Follow up 2.....	57
Reliability between Sleep Diaries and VSG data.....	57

Reliability of VSG Data	57
Effect of Doll and Behavioural Intervention on Sleep as measured by Parent	
Reported Sleep Diaries	58
Doll and parent report diaries.	61
Sleep onset delay.....	61
Number of night wakes.....	62
Duration of night waking.....	62
Behavioural intervention and parent report diaries.....	63
Sleep onset delay.....	64
Number of night wakes.....	64
Night waking duration.	64
Videosomnography Measures of Sleep States	65
Effect of Doll and Behavioural Intervention on Sleep State Variables as measured by	
Videosomnography	66
Doll intervention and VSG data.....	70
Largest number of AS-QS transitions before wake.	70
Number of sleep state transitions before wake.	70
Quiet sleep.	71
Longest sleep period.	71
Wake duration.....	71
Sleep efficiency.....	72
Parental intervention	72
Behavioural intervention and VSG data.	73
Largest number of AS-QS transitions before wake.	73
Number of sleep state transitions before wake.	73

Quiet sleep.	73
Longest sleep period.	73
Wake duration.	74
Sleep efficiency.....	74
Parental intervention.	74
Parental response delay.....	74
Parent Report of Doll Effectiveness	75
Chapter Four	76
Discussion.....	76
Research Questions Answered.....	76
Research Question One.....	76
Research Question Two.	77
Effect on Parenting Ppractices	77
Why Was The Doll Not Effective?	78
Parent Report of Doll Effectiveness	79
Behavioural Intervention and Sleep.....	79
Behavioural intervention and parent report sleep diaries.	79
Behavioural intervention and sleep state organisation change.	80
Was the behavioural intervention effective?	81
Limitations.....	82
Future Research	83
Strengths of the Study	84
Conclusion	84
References.....	86

Appendix A: Recruitment Poster	95
Appendix B: Information Sheet.....	96
Appendix C: Ethics Approval Letters.....	99
Appendix D: Consent forms for participants	102
Appendix E: Sleep Diary	104

List of Tables

Table 1: Participant information	44
Table 2: Sleep wake state criteria for assessing infant sleep	47
Table 3: Definition of variables derived from videosomnography data.	48
Table 4: Initial interview questions.....	49
Table 5: Exit interview questions	49
Table 6: Reliability between parent report sleep diaries and VSG data.	57

List of Figures

Figure 1: Sleep onset delay as measured by parent report sleep diaries across all phases	58
Figure 2: Number of night wakes as measured by parent reported diaries across all phases ..	59
Figure 3: Night waking duration as measured by parent report diaries across all phases	60
Figure 4: Number of sleep state transitions from VSG data	66
Figure 5: Number of AS-QS transition from VSG data	66
Figure 6: Percentage of sleep time spent in quiet sleep from VSG data.....	67
Figure 7: Longest sleep period from VSG data	67
Figure 8: Wake duration from VSG data.....	68
Figure 9: Sleep efficiency from VSG data.....	68
Figure 10: Duration of Parental Intervention from VSG data.	69
Figure 11: Delay of parental response following a signal from infant from VSG data.....	69

Acknowledgements

To my supervisors, Associate Professor Karyn France and Dr Laurie McLay, thank you for sharing your extensive knowledge and expertise with me. Karyn, a gigantic thank you for unwavering support throughout this thesis journey. Your willingness to go above and beyond for your students does not go unnoticed. Laurie, thank you for your valuable time you spent reading my drafts. A big thank you to Professor Neville Blampied also, for his assistance with graphing and all things Sigma Plot.

To my family, whose immense belief in me has helped me achieve things I once never thought possible. Mum, thank you for your never-ending well of support, love and faith. Your ability to get me through every road block on this journey was invaluable. And to my brother Andrew, for always reminding me to laugh no matter how stressed I was.

To my partner Cody, thank you for your incredible patience and continual reassurance that this thesis would one day be a finished product.

Lastly a big thank you to all my friends who leant an ear on many occasion. And to all of the CFPY girls, thank you for the laughs, support and encouragement along the way.

Abstract

Infant sleep patterns are one of the most common sources of concern for parents. While there is a wide range of products and information claiming to support infant sleep, available to parents, the empirical evidence supporting these can be varied. This study aims to investigate the effectiveness of a heart-beating, breathing doll (Lulla Doll) on infant sleep. Five infants aged between 4 and 8 months and their parents (who wished to use the doll) were recruited through social media. The participants were followed, in a multiple-baseline across participants design through 3 phases, baseline, intervention and follow up. Infant sleep was tracked through the use of prospective parent reported sleep diaries and objective videosomnography (VSM) recordings of sleep states. Two families chose to employ a behavioural intervention following the use of the doll and data collection continued in these cases. Results of the study showed no clear effect of the doll on infant sleep, either in parental diary recordings or in VSM sleep states. The behavioural intervention was effective in reducing the number of night wakings, and duration of night wakings for one participant as well as changing her VSM sleep states. These changes in sleep state organisation included an increase in the number of active to quiet sleep transitions before wake, longest sleep period and sleep efficiency and a decrease in wake duration. Behavioural intervention resulted only in changes in sleep onset delay for the other participant. Results are discussed in the light of this finding and suggest future directions which may contribute further to the understanding of the effect of environmental stimuli on infant sleep.

Chapter One

Introduction and Literature Review

Sleep can be defined as a reversible behavioural state, which is the product of a complex interaction between physiological and behavioural processes (Carskadon & Dement, 2005). An essential ingredient for human life at any age, sleep is particularly prominent in the first year of life when infants spend most of their time asleep (Ednick et al., 2009). Research has established that some measures of sleep, such as sleep efficiency, total sleep time and number of night wakings, have a close association with cognitive development in early childhood (Bernier, Carlson, Bordeleau, & Carrier, 2010; Gertner et al., 2002; Scher, 2005). In their study of children from infancy to 3 years of age, Bernier et al. (2010) reported an association between total sleep time at night at 12 months and better performance in executive functioning tasks at 26 months of age. In their sample of 10 month olds, Scher (2005) also reported an association between increased motor activity in sleep, more fragmented sleep and lower scores on the mental developmental index of the Bayley Scales of Infant Development.

Quality of infant sleep has also been documented to have potential consequences for the wider family system. From their survey of Australian mothers, Martin, Hiscock, Hardy, Davey, and Wake (2007), concluded that mothers of infants (mean age of 8.8 months, SD = 2.6) with parent reported sleep difficulties are more likely to report poor mental health than mothers of infants who do not believe their infants to have a sleep problem. In fact, it has been reported that mothers who report their infant to have difficulties with sleep are twice as likely to report clinically significant depressive symptoms than mothers who do not report a sleep problem (Hiscock & Wake, 2001; Martin et al., 2007). In their cross cultural survey of 10,085 parents, Mindell, Sadeh, Kwon, and Goh (2015) identified the existence of an

association between child sleep patterns and maternal sleep patterns as well as association between quality of child sleep and maternal functioning across 13 countries. They report a significant association between maternal sleep patterns and child sleep patterns for bedtime, wake-time, number of night wakes and total night time sleep, demonstrating the inter-relation of sleep patterns between children and their mothers. The association between maternal sleep patterns and child sleep patterns was identified to be similar in both predominantly Caucasian and predominantly Asian countries. A discrepancy was however reported for the strength of which mothers rated the relationship between their child's sleep and their own poor sleep with mothers in predominantly Caucasian countries rating the relationship stronger than mothers from predominantly Asian countries.

Across all countries surveyed, 54.7% of mothers reported their child's sleep to be problematic, 44.2% of mothers surveyed reported that their infant's sleep influences their own sleep, and 30.1% of mothers also reported that they believe their child's sleep pattern affects their ability to function during the day (Mindell et al., 2015). Of all parents who were surveyed, parents of younger children (under 35 months of age) reported significantly more impact from their child's sleep on their own sleep and daytime functioning than parents of older children (36-59 months). Child night waking was reported to be the factor which was most strongly associated with poor maternal sleep (Mindell et al., 2015).

Although there is a significant amount of research detailing the relationship[between infant sleep and maternal mental health, only one research article documents the association between paternal mental health and infant sleep. Nonetheless, Cook et al. (2017) also report an association between infant sleep and paternal mental health. In their sample of 102 fathers, fathers who reported their infant to have a sleep problem at both 4 and 6 months of age were found to have an increase in depressive symptomology when compared with fathers who did

not report their infant to have a sleep problem. At 4 months of age, 10% of these fathers had scores on the Edinburgh Postnatal Depression Scale that met criteria for a diagnosis of post-natal depression, and at 6 months of age, 4% of fathers continued to have scores high enough to meet criteria of post-natal depression. Cook et al. (2017) also found that fathers who reported their infant to have a sleep problems showed increased doubt regarding their ability to parent their child at bedtime and that they also reported poorer personal sleep than fathers who did not report their infant to have a sleep problem.

Given that sleep consolidates most rapidly during first four months of life (Henderson, France, Owens, & Blampied, 2010), it is not surprising that the association between infant sleep and parental functioning is found to be the strongest amongst parents of younger infants (Mindell et al., 2015). Research demonstrates that whilst uninterrupted sleep is not uncommon prior to four months of age, by five months of age, 50% of infants are able to meet the criteria of sleeping through the night between 10pm and 6am (Henderson et al., 2010). Despite this, some infants fail to meet this criterion in the first year of life and therefore parental complaints regarding their infant's sleep are common throughout the first year of life (Eckerberg, 2004; Sadeh & Anders, 1993). Parental complaints often refer to difficulties getting their child to fall asleep promptly and independently (sleep onset difficulties), as well as difficulties with recurrent night wakings (sleep continuity problems) or a combination of both difficulties (Eckerberg, 2004; Sadeh & Anders, 1993). The common feature of both of these complaints is that they both involve and reflect the infant's capability to self-soothe during transition into sleep (Goodlin-Jones, Burnham, Gaylor, & Anders, 2001)

Due to the potential consequences poor infant sleep can have for infants and their families there has been a considerable effort by researchers to identify variables which may

influence the development of infant sleep, including focus on both biological (Halpern, Anders, Garcia Coll, & Hua, 1994; Serón-Ferré, Torres-Farfán, Forcelledo, & Valenzuela, 2001; Spruyt et al., 2008) and environmental factors (Brackbill, Adams, Crowell, & Gray, 1966; Brescianini et al., 2011; Sadeh & Anders, 1993). Biological factors that have been identified as playing a role in the development of sleep-wake patterns include the development of a circadian rhythm (Guyer et al., 2015) as well as the relationship between infant temperament and infant sleep development (Halpern et al., 1994; Jian & Teti, 2016; Spruyt et al., 2008). Environmental influences identified include caregiving behaviours (Burnham, Goodlin-Jones, Gaylor, & Anders, 2002; Morrell & Cortina-Borja, 2002; Touchette et al., 2005), parental cognitions and beliefs (Tikotzky & Sadeh, 2009; Zaidman-Zait & Hall, 2015), environmental noise and stimuli (Ingersoll & Thoman, 1994; Schmidt, Rose, & Bridger, 1980; Tulloch, Brown, Jacobs, Prugh, & Greene, 1964) and caregiving procedures such as the skin to skin contact involved in “Kangaroo Care” (Feldman & Eidelman, 2003; Ludington-Hoe et al., 2006).

Difficulties with infant sleep are common complaints for which parents seek assistance from a variety of health care professionals and from other informal avenues in the public domain such as online websites, DVD’s and self-help books (Fisher et al., 2011). Currently the information and advice that is available to parents from both healthcare professionals and other informal sources is widely varied according to different philosophies and beliefs about what is appropriate and beneficial for infants (Chapman, 2017; Fisher et al., 2011; Hiscock & Fisher, 2015). In order to support infants and their families, it is important and beneficial for advice to be evidence based.

This thesis investigates the effectiveness of a popular tool marketed to improve infant sleep, the Lulla Doll. The Lulla Doll, by RoRo, is a sleep companion which features an 8

hour recording of a heartbeat and breathing sound (Lulladoll.com, 2016). The Lulla Doll is marketed to provide infants with a sense of comfort and a feeling of closeness to parents when their parents are away (Lulladoll.com, 2016). The Lulla Doll website states that research on closeness between infants and parents has been found to increase periods of uninterrupted sleep and create healthier sleep patterns (Lulladoll.com, 2016). Significantly popular in New Zealand, the first shipment of Lulla Dolls sold out promptly and a subsequent 1200 pre-orders were placed (Nicol, 2016). The Lulla Doll is just as popular worldwide, with prices reaching up to \$350 USD on eBay, far above the retail price of \$69 USD (Mattern, 2017).

The following study evaluates the effectiveness of the Lulla Doll with a sample of 5 infants aged between 4 and 8 months of age. This first chapter begins by discussing methods which are used to assess sleep, defining different aspects of sleep which are assessed in research and detailing the developmental trend which is observed for these aspects of sleep. Understanding different methodologies and the various aspects of sleep is important for interpreting research, as studies often vary in their methodology as well as what aspect of sleep they assess. The chapter will then examine factors which have been found to be associated with the development of infant sleep including biological and environmental factors. The chapter concludes after reviewing research on Kangaroo Care and a similar sleep companion called the breathing bear.

Sleep Research Methodology

Multiple methodological options are available for measuring infant sleep, each with their own advantages and limitations. Commonly employed methodologies include polysomnography, videosomnography, direct behavioural observations, actigraphy and sleep diaries (Sadeh, 2015), however the most commonly employed methodology in the home

setting is actigraphy or videosomnography combined with parent diaries . (Burnham et al., 2002; France & Blampied, 2005; Henderson et al., 2010; Henderson, France, & Blampied, 2011; Sadeh, 2004, 2011; Sadeh, Hauri, Kripke, & Lavie, 1995; So, Michael Adamson, & Horne, 2007; Tikotzky & Sadeh, 2009). The following section discusses all methodologies and the advantages and limitations to each.

Polysomnography. Polysomnography is considered the gold standard of sleep wake assessment tools for sleep research and usually includes recordings of electrical brain activity (EEG), muscle activation (EMG), eye movements (EOG), breathing, oxygen saturation and video recording. It is most commonly conducted in the laboratory setting and involves electrodes and sensors being attached to a child for one to two nights. Whilst providing rich and detailed data, polysomnography is a costly endeavour and also requires subjects to sleep in an unfamiliar setting. Sometimes this results in an atypical representation of sleep for infants and young children (Sadeh, 2015).

Videosomnography. Videosomnography uses video equipment to observe sleep. By using videosomnography, sleep states, infant and child behaviour, parental intervention and self-soothing skills can all be identified, a major advantage of videosomnography (Burnham et al., 2002). Another benefit of videosomnography is the ability to integrate the equipment easily into the infant or child's natural environment. Time lapse video recordings have also been found to correspond well to polygraphic recordings, the gold standard of sleep assessment, with an overall correlation of .79 with a sample of very young infants, aged between 2 and 8 weeks of age (Anders & Sostek, 1976).

Direct behavioural observations. Direct behavioural observations, like videosomnography, is a methodology which can also be employed in the natural home environment to assess sleep, Direct behavioural observations have some similar advantages

to videosomography (e.g., can be done in natural environment). However they are very labour intensive, and usually only employed for several hours at a time, most commonly during the day, and often only used for infants or very young children. When employing this method, it is important to consider the effect of interference on results which may be caused by having an observer present (Sadeh, 2015).

Sleep diaries. Sleep diaries are also often used for sleep assessment in the home setting and are often used with both infants and young children. Sleep diaries can record information regarding a variety of sleep related variables including sleep schedule, sleep duration, wakings from sleep and behaviour prior to sleep onset and upon waking. While sleep diaries are cost effective their reliance on compliance from participants or parents to complete can compromise reliability and be a burden for participants. Parent reported sleep diaries are also limited to the experience the parent has of infant sleep so tend to only reflect signalled wakings (Sadeh, 2015; Sadeh & Mindell, 2016).

Actigraphy. Actigraphy is the use of a wrist device, similar to a watch which continuously monitors body movements and provides information regarding sleep, such as sleep states and sleep wake patterns. Actigraphic devices can be connected to either the wrists or ankles of infants. While actigraphy is a cost effective and non-intrusive methodology, it cannot provide examples of specific infant behaviour, such as signalling or parental behaviour, such as soothing methods or periods of motionless wakefulness (Sadeh, 2015). The validity of actigraphy has been assessed by multiple studies and compared to several other types of sleep assessment (Mueller, Hemmi, Wilhelm, Barr, & Schneider, 2011; Sadeh, 1996; So, Buckley, Adamson, & Horne, 2005; So et al., 2007). So et al. (2005) compared actigraphy with the gold standard of sleep assessment tools, polysomnography, with a sample

of infants aged up to 6 months of age and found agreement rates of 89-94%, indicating good validity.

Several studies have also compared actigraphy data with parent reported sleep diaries for infants (Mueller et al., 2011; Sadeh, 1996; So et al., 2007). These studies have consistently reported that when compared with actigraphy, parental sleep diaries were found to over estimate sleep time and underestimate wake time when compared to the actigraphy which reported more wake time and less sleep time. This is likely to reflect the fact that parents are unlikely to report wakings where their infant does not signal (Sadeh & Mindell, 2016; So et al., 2007). These findings highlight the importance of including an objective measure such as actigraphy or videosomnography alongside parent reported sleep diaries. It also however, highlights a potential disadvantage of actigraphy data, compared with videosomnography data, which is the inability of actigraphy to distinguish between signalled and unsignalled wakings. Some concern has also been noted regarding the ability of actigraphy to distinguish between times of wake with low levels of activity and times of sleep with high levels of activity. (Sitnick, Goodlin-Jones, & Anders, 2008).

Development of Sleep

At birth, infants typically spend 16-17 hours sleeping in periods of 3-4 hours. These periods of 3-4 hours are initially distributed evenly across the 24-hour period but change within the first weeks to a diurnal pattern with longer sleep at night. At one year of age, infants sleep for a similar duration of approximately 14-15 hours, however the majority of this sleep is now observed to occur over the night time period (Galland, Taylor, Elder, & Herbison, 2012). This shift from multiphasic distribution of sleep in early infancy to diurnal, consolidated sleep during the night in later infancy has been of much interest to parents and researchers and therefore has garnered significant research. The next section of this chapter

will discuss various aspects of infant sleep which are commonly referred to in sleep research and the developmental trends they follow.

Longest sleep period. The longest sleep period (LSP) is defined as the longest sustained period of uninterrupted sleep an infant is capable of maintaining. It represents the infant's physiological ability to maintain continuous sleep with the absence of wakefulness (Henderson et al., 2011). Infant sleep research has established that the longest sleep period of an infant increases significantly in the first part of the year and then levels off for the remainder of the first year of life (Burnham et al., 2002; Henderson et al., 2011). In 6 out of 7 studies reviewed by Henderson et al. (2011) the greatest rate of change for the longest sleep period was observed to occur in the first 3 months of life, with the LSP increasing from 3.0 - 4.5 hours at 1 month of age to a mean LSP of 6.2 hours at 2 months of age. All studies in the review which included data at 3 months of age showed the maximum rate of change to conclude at this time, with the rate of increase for the LSP between 3 and 12 months observed to be less than 30 minutes.

Longest self-regulated sleep period. The longest self-regulated sleep period (LSRP) is defined as the longest period of sleep and quiet awake an infant can maintain over the night time period. In contrast to the LSP measure which solely represents the physiological ability of the infant, the LSRP measures reflects both the LSP, being the infant's physiological ability to sleep, as well as the infant's ability to self regulate. The LSRP includes the time in which the infant is awake but quiet, and then is able to reinitiate sleep independently without needing to signal for parent support to reinitiate sleep (Henderson et al., 2011). In practical terms, it is the time between when an infant goes down to sleep till the time which they signal by crying or calling out to their parents. In their review, Henderson et al. (2011) report that similar to the LSP, the LSRP increases in length most rapidly in the first 4 months of life,

with the most significant increase between 1 and 2 months of age. The mean LSRP is reported to range from 4.62 to 5.5 hours at one month of age to between 5.46 and 8.8 hours at 2 months of age and then to increase to between 7.06 and 10.52 hours at 3 months of age. However, similar to the LSP, the LSRP is then seen to plateau following this period of significant growth. The plateau is observed to occur between the ages of 4 and 8 months of age when the mean LSRP increases only by 15 minutes or less. In contrast to the LSP however, there is a steady increase following the plateau between the ages of 9 and 12 months where the mean LSRP increases by less than 25 minutes to just over an hour. To accurately record this measure, it is imperative to use a sleep methodology which enables researchers to employ a method such as videosomnography or visual observations which enable signalled wakings to be distinguished from unsignalled wakings.

Sleeping through the night. The ability for infants to sustain sleep without requiring parental intervention during the nocturnal period or to ‘sleep through the night’, is a popular topic among parents, clinicians and researchers alike. In particular, many parents are interested in establishing the time at which their infant is likely to ‘sleep through’.

For many years, researchers defined ‘sleeping through the night’ as sleeping uninterrupted from 12.00 to 05.00 or for 5 hours at time for at least 6 out of 7 nights for 4 weeks, a definition which originated from Moore and Ucko (1957). More recently however, new definitions have been engaged, such as sleeping 8 hours uninterrupted and sleeping 8 hours between the times of 22.00 and 06.00 (Henderson et al., 2010). The latest definition offered, of sleeping uninterrupted between the hours of 22.00 and 06.00, has been suggested to be a socially valid replacement of Moore and Ucko (1957) definition as it more closely aligns with the sleeping period of the parents and family of the infant (Henderson et al., 2010).

In their study, Henderson et al. (2010) addressed the popular question of when most infants will ‘sleep through’ by following 75 infants and their ability to meet the three criteria described above across the first year of life. Results of the study showed there was no significant difference between an infant’s ability to meet the 5-hour criterion or 8 hour criterion, with most infants meeting both these criteria by 2 months of age. In contrast, infants were slower to meet the third, and specific time dependant definition of sleeping between 22.00 and 6.00. However by 5 months of age 53% of infants were able to meet this criterion (Henderson et al., 2010). In summary, research on ‘sleeping through the night’ substantiates that most infants are able to ‘sleep through the night’ or for 8 hours, by the age of 6 months of age (Henderson et al., 2011).

Night wakings. In addition to documenting the infant’s ability to sleep through the night, researchers have also been interested in documenting developmental patterns for arousals in infants throughout the first year of life. Like sleeping through the night, this is also a topic which is often of interest to parents.

While methodological issues hinder agreement upon the specific numbers of awakenings infants experience throughout their first year, some research reports a decrease in the number of awakenings experienced by infants across their first year of life (Fagioli, Ficca, & Salzarulo, 2002; Galland et al., 2012; So et al., 2007; Weinraub et al., 2012). Other studies however, do not detect a change in the number of awakenings throughout the year (Anders, Halpern, & Hua, 1992; Goodlin-Jones et al., 2001). These studies which do not detect a fluctuation in night waking do identify a change in related variables, including time out of cot (Goodlin-Jones et al., 2001) and number of signalled vs unsignalled wakings (Anders et al., 1992). Goodlin-Jones et al. (2001), in their sample of 80 infants described a significant decrease in the amount of time infants were out of the crib over the first year of life.

(Goodlin-Jones et al., 2001). They report that although the mean number of awakenings at 3 months of age remained the same at 12 months of age, the amount of time the infant was removed from the cot significantly decreased between 3 and 12 months of age. It is likely this decrease in OOC time indicates the emergence of self-soothing tendencies over time and a change in the type of awakening the infant had. As time went on it appears infants were less likely to need to be removed from the cot by their parents following an awakening, most likely due to the development of self soothing tendencies and increase in non signalled wakings and a decrease in signalled wakings. Using videosomnography, Goodlin-Jones et al. (2001) were able to identify infants as either, 'self-soothing', those infants who were able to reinitiate sleep after waking without parental intervention or 'non-self soothing' those who required parental intervention to return to sleep. They reported that infants belonging to the 'self-soothing' group were removed from the cot for 1.4% of time compared to infants in the 'non-self soothing' group who were removed on the cot 5.3% of time.

Anders et al. (1992) also reported, that infants generally wake at least once or more at both 3 weeks and 3 months of age, and they also noted a change in the type of wakes occurring. They reported that at 3 weeks of age, 90% of infants signalled for parental attention following a wake, yet at 3 months 50% of the infants were able to reinitiate sleep independently. By 8 months of age, 52% of infants no longer signalled subsequent to an arousal (Anders et al., 1992). Burnham et al. (2002) also reported that in general there was no difference in the number of wakings between 3 and 12 months of age but there was an increase in self-soothed awakenings from 1 month of age where 27.6% of the time infants would put themselves back to sleep, compared to 12 months of age when infants returned to sleep independently 46.4% of the time.

These studies emphasise the importance of identifying signalled vs unsignalled wakes and the developmental course that is evident in these types of wakes. They also highlight the effect the type of wake, whether signalled or unsignalled, can have on other sleep measures, such as percentage of night spent out of cot. The type of wake experienced is also likely to affect the parents perception of the infants night time sleep. As some methodologies do not provide the ability to differentiate between these types of wakings it is important to consider the sleep measures that are used.

Sleep Wake States

Newborn infant sleep can be categorised into three different types; active sleep, quiet sleep and indeterminate sleep (Brackbill et al., 1966; Davis, Parker, & Montgomery, 2004; Detterman, 1978; Jian & Teti, 2016; Zaidman-Zait & Hall, 2015). Other variables that are also often measured in sleep research include: out of cot time (OOC) and total sleep time (TST) and percent of signalled vs unsignalled wakings. Researchers have been able to document the changes that are commonly observed in the distribution and duration of these states and variables across the first year of life.

Awake/Wakefulness. Time spent in the awake state is defined as any time the infants spend in the cot awake, during this time they may be lying quietly, moving about or making noise (Anders & Keener, 1985). Anders and Keener (1985) and Burnham et al. (2002) both documented the developmental course of different sleep wake states over the first year of life in their research. From their longitudinal research featuring 40 full term infants, Anders and Keener (1985) concluded that the percentage of time infants spent in wakefulness remained relatively constant in the early part of the year and then increased slightly in the last half of the year, reflecting the emergence of night waking in some infants. In their cross-sectional

research, Burnham et al. (2002) reported that there was no significant change evident in the proportion of time infants spent awake during the night over the course of the year.

Out of crib time (OOC). Out of crib time is a measure which refers to any time that the infant is removed from the cot, such as for feeding, soothing or any other caretaking task (Anders & Keener, 1985). Out of crib time has been found to decrease as infants mature across the first year of life (Anders & Keener, 1985; Burnham et al., 2002; Goodlin-Jones et al., 2001). It has been suggested that this decrease is most significant in the first portion of the year, with one study observing a significant decrease during the first 3 months followed by a slight levelling off and another observing a significant decrease in the first 6 months followed by a subsequent levelling off for the following 6 months (Anders & Keener, 1985; Burnham et al., 2002). This observed decrease in out of cot time has been noted to be associated with the development of self-soothing capacities, which are observed to increase with age. As discussed previously in the chapter, infants who are able to self-soothe following an awakening are removed from the cot significantly less than those infants who require parental intervention to reinitiate sleep (Goodlin-Jones et al., 2001).

Active and quiet sleep. Infant's sleep architecture comprises three types of sleep, quiet sleep or NREM (non rapid eye movement) sleep, active sleep or REM (rapid eye movement) sleep and indeterminate sleep. Quiet sleep or NREM sleep is described as being characterised by minimal muscle movement and rhythmic slow abdominal breathing (Davis et al., 2004; Sadeh, Acebo, Seifer, Aytur, & Carskadon, 1995; Thoman, 1990). Active sleep, or REM sleep, however is described as being characterised by occasional sucking motions, smiling, vocalizations, sighs, sobs, twitching and limb movements. Infants may also briefly cry out or grunt during REM or active sleep (Davis et al., 2004; Sadeh, Acebo, et al., 1995; Thoman, 1990). Indiscriminate sleep, or transitional sleep, is infant sleep that can not be

classified by polysomnography as active or quiet sleep. As an infant matures however, indiscriminate sleep gradually declines and sleep becomes easily defined as either active or quiet sleep (Davis et al., 2004). At around 3 months of age, the stages 1-4 of NREM sleep also become distinguishable and identifiable.

During the first few weeks of life an infant has a sleep cycle which consists of both quiet sleep (NREM) and active sleep (REM) phases which are in equal proportion to one another. However, time spent in active sleep gradually declines as infants mature (Anders et al., 1992; Anders & Keener, 1985; Burnham et al., 2002) while time spent in quiet sleep increases (Anders et al., 1992; Anders & Keener, 1985; Burnham et al., 2002). By approximately 8 months of age, active or REM sleep has decreased to one third of the total sleep cycle and quiet sleep or NREM sleep has increased to two thirds of the total sleep cycle (France & Blampied, 1999) and by the end of the first year the percentage of quiet sleep in the nocturnal period becomes greater than the percentage of active sleep (Anders & Keener, 1985)

In comparison to adults whose sleep periods generally consist of 5-6 sleep cycles of approximately 90 minutes (Mitru, Millrood, & Mateika, 2002), newborn infant sleep periods only feature one or two sleep cycles of approximately 50-60 minutes, therefore resulting in shorter sleep periods and the need for increased sleep periods during early infancy (Davis et al., 2004).

Factors that Influence Sleep Development in Infancy.

Whilst there has been a significant amount of research documenting general developmental trends for sleep during infancy, there has also been a substantial amount of research aiming to identify factors that may explain individual differences in sleep development. A range of both biological and environmental factors have been identified as

being associated with the development of infant sleep. Further information detailing the relationship between these factors and infant sleep will be discussed below.

Biological Influences.

The following section will discuss the influence of infant temperament and circadian rhythm on the development of infant sleep.

Circadian Rhythm and Entrainment. As noted, infant sleep-wake patterns have been observed to change significantly throughout the first year of life, with sleep becoming increasingly more consolidated over the night time period and periods of wakefulness increasing in length during the day as infants mature. Research has identified that this consolidation of sleep in the night time period is partly influenced by the development of a circadian rhythm. Circadian rhythms are patterns spanning over 25 hours which have been developed by our ‘biological or circadian clock’, also known as the suprachiasmatic nucleus (SCN) (Serón-Ferré et al., 2001). The SCN is located in the anterior hypothalamus. Circadian rhythms are responsible for regulating many physiological rhythms such as body temperature, heart rate, blood pressure, hormone secretion as well as sleep wake patterns (Shinohara & Kodama, 2011). While infants are born with the capacity for a sleep wake circadian rhythm, it is poorly developed at the time of birth and therefore this results in infants initially displaying sleep patterns which are incompatible with those of their parents (Thomas, Burr, Spieker, Lee, & Chen, 2014).

The timing at which the sleep wake rhythm is established is thought to either be related to the amount of time exposed to certain environmental cues or to reaching a particular age at which the required brain functions have developed (Guyer et al., 2015). Guyer et al. (2015) investigated the emergence of the sleep wake rhythm by following three groups of infants. These included pre-term infants who were exposed to two types of light

and a group of full term infants. The two types of light included cycled light and dim light. In the cycled light condition environmental conditions were altered significantly to clearly differentiate between day and night time. Between 7am and 7pm, curtains were removed and over-head lights were turned on. Between 7pm and 7am, curtains were closed and lights turned off. In the dim light condition, the bed curtains were closed at all times the infants were asleep and were only opened during feeding periods which occurred every 3 to 4 hours for several minutes. Results from the study found that when compared at a equivalent age, preterm infants in both the dim light and cycled light condition showed a stronger 24-hour sleep-wake rhythm than term infants, as demonstrated by longer night time sleep duration. In addition, infants in the cycled light condition showed even longer night time sleep duration than infants in the dim light condition. These findings support the hypothesis that circadian rhythm entrainment is more heavily influenced by time or exposure to environmental cues than by age related changes.

To develop, or entrain the circadian clock to match the 24 hour day-night period of human life, the SCN is dependent on receiving inputs from the environment (Rivkees, 2003). These inputs or environment cues are called zeitgebers (Roenneberg, Kumar, & Merrow, 2007). Zeitgebers or environmental cues include things such as light, temperature or social factors such as timing of different activities (McGraw, Hoffmann, Harker, & Herman, 1999). Light however has been identified as the most important zeitgeber for entraining the circadian rhythm to reflect the relevant day night period experienced by the individual (Roenneberg, Kuehnle, et al., 2007).

Infant Temperament. Temperament is a term which refers to genetically determined behavioural characteristics of an individual (Ednick et al., 2009). It has been identified as an intrinsic infant factor which plays a role in the transactional model of infant sleep as

developed by Sadeh, Tikotzky, and Scher (2010). Temperament is a construct which has multiple definitions but is often conceptualised as consisting of multiple dimensions (Rothbart, 2007; Thomas & Chess, 1977). Multiple studies report associations between different dimensions of temperament and infant sleep, however there is significant variance between studies regarding what aspects of temperament correlate with different aspects of sleep (Halpern et al., 1994; Spruyt et al., 2008). These variations in methodology and measures as well as the complexity of defining temperament for research are important to note when considering research findings in this area.

The complexities of researching the association between temperament and infant sleep is demonstrated in the results of Halpern et al. (1994). In short, markedly different results may be obtained when temperament is measured using objective measures compared to using parental report. When assessing temperament using a behavioural paradigm which involved presenting infants with a variety of stimuli, Halpern et al. (1994) report findings that infants who spent more time awake at 3 weeks of age had higher irritability and inhibition scores at 3 months of age when temperament was measured by a behavioural assessment. Furthermore, Halpern et al. (1994) also reported that at 3 months of age infants who were awake more during the night were rated less sociable and those with a shorter longest sleep period were more difficult to calm when they cried and demonstrated less approach behaviour. In contrast, when assessing temperament by parental ratings, the association between temperament and sleep was not as strong as when assessed with the behavioural observation ratings. Instead the only correlation between temperament and sleep, when measured by parental report, was between increased quiet sleep and higher ratings of infant dullness.

Spruyt et al. (2008) also evaluated the relationship between infant temperament and sleep by employing parental assessment of temperament. Sleep was measured using actigraphy. Sleep and temperament were assessed once a month across the first 12 months of life for a group of infants. In contrast with Halpern et al. (1994), Spruyt et al. (2008) report a strong correlation between parent reported temperament and sleep. In their study they found an association between ratings of 'easy temperament', as characterised by increased approachability, rhythmicity, adaptability and low distractibility and increased sleep duration. More specifically, results showed that at 3, 6 and 11 months of age, higher rates of night time sleep was correlated with higher rates of approachability, an aspect of temperament. At 3 months of age there was also an association between increased 24-hour sleep and higher rates of approachability and at 6 months of age, increased 24-hour sleep was also associated with increased rhythmicity and low distractibility.

While these studies have reported on correlations between infant temperament and sleep alone, in their study Jian and Teti (2016) investigated the role of temperament as a moderating factor. Jian and Teti (2016) hypothesised that temperament may moderate the relationship between maternal emotional availability (EA) and infant sleep. Jian and Teti (2016) proposed that evaluating temperament and investigating its potential role as a moderating factor enables us to consider temperament in a potentially more complex and transactional way than previous research has been able to do. Measures in the study included actigraphy for sleep, observed maternal emotional availability from video recordings and maternal reports of infant temperament. Contrary to the hypothesis of the researchers, results revealed no predictive relationship between mother report temperament factors at three and six-month of age and infant sleep characteristics such as time spent asleep, wake duration and sleep efficiency from one to six months of age. This finding is consistent with the findings of

Halpern et al. (1994) who also did not detect a relationship between parental ratings of temperament and infant sleep.

Also contrary to the authors' hypothesis, negative affectivity or orienting/regulation did not moderate the relationship between sleep development and maternal EA at bedtime. The authors suggest that this result reflect the possibility that this aspect of temperament is not relevant until a later developmental age. The study did however identify a moderating effect of infant positive emotionality between maternal bedtime EA and sleep length. The authors found that infants with high levels of surgency were more receptive to positive effects of maternal EA at bedtime when compared with infants with lower surgency. In conclusion these studies suggest that while temperament likely has a role within the development of infant sleep it is complex in nature and therefore difficult to conceptualise in research.

Environmental Influences.

Research utilising monozygotic and dizygotic twins has helped researchers understand the contributions of genetic and environmental factors to sleep behaviour. Twin research suggests that while both genes and environmental factors play a role in sleep behaviour, environmental factors have a stronger influence over many sleep components (Brescianini et al., 2011; Fisher, van Jaarsveld, Llewellyn, & Wardle, 2012). These include morning wake time, night-time sleep, duration of daytime naps and sleep disturbance (Brescianini et al., 2011; Fisher, van Jaarsveld, et al., 2012).

Subsequently, research has identified and investigated the relationship between many different environmental variables and infant sleep. Such as the relationship between infant sleep and caregiving strategies (Adair, Bauchner, Philipp, Levenson, & Zuckerman, 1991; Morrell & Cortina-Borja, 2002; Touchette et al., 2005), maternal cognitions and beliefs

(Sadeh, Flint-Ofir, Tirosh, & Tikotzky, 2007), parental tolerance to cry (Sadeh et al., 2016), environment noise including heartbeat sound and white noise (Brackbill, 1970; Brackbill et al., 1966; Detterman, 1978) and also between specific parental practices following birth (Ferber & Makhoul, 2004; Ludington-Hoe et al., 2006) The following will discuss these relationships in further detail.

Caregiving behaviour. The transactional model of infant sleep developed by Sadeh and Anders (1993) and adapted by Sadeh et al. (2010) describes parental behaviour as the most direct and immediate link mediating infant sleep. This relationship is demonstrated by numerous studies which report a significant association between nocturnal parental caregiving behaviours and infant sleep quality (Adair et al., 1991; Anders et al., 1992; Touchette et al., 2005). In particular, research demonstrates a relationship between active soothing strategies employed by parents such as rocking, holding or feeding and increased night wakings (Anders et al., 1992; Burnham et al., 2002; DeLeon & Karraker, 2007; Morrell & Cortina-Borja, 2002; Tikotzky & Sadeh, 2009; Touchette et al., 2005). Morrell and Cortina-Borja (2002) found in their longitudinal study, which investigated common strategies used by parents in sleep routines, that higher use of active physical comforting strategies, such as rocking or cuddling a child to sleep and low use of autonomy encouraging strategies, such as using a musical toy, providing a special toy or leaving the child to cry were associated with higher infant sleep problems as measured by the Infant Sleep Questionnaire (Sadeh, 2004). In addition to an association between the types of strategies employed by parents and infant sleep quality, Burnham et al. (2002) have also reported an association between the timing of parental intervention and sleep problems in their study of 87 infants. Utilising time lapse video recordings at 5 ages, Burnham et al. (2002) observed an association between the amount of time between an infant awakening and signalling and a

parental response at 3, 6 and 9 months of age and self-soothing behaviour at 12 months of age. The longer the duration between signalling and parental intervention, the more likely the infants were to be self-soothing following wakes at 12 months of age. A similar finding was reported by St James-Roberts, Roberts, Hovish, and Owen (2017) who carried out a longitudinal study with 120 infants and their parents. St James-Roberts et al. (2017) followed 2 groups of participants for 6 months. Data was collected when the infants were aged 2 weeks, 5 weeks, 3 months and 6 months of age. The first group of participants were referred to as 'bed-sharing parents'. These were parents who expressed they intended to co-sleep with their infant before their infants' births and who researchers predicted would engage in 'infant-cued parenting'. The second group was called the 'general-population' group and were parents recruited from maternity wards of a general community hospital. Like Burnham et al. (2002), St James-Roberts et al. (2017) also utilised video recordings of sleep, in addition to parent report diaries in their study. St James-Roberts et al. (2017) report that infants whose parents consistently employed a short delay between their infant waking and feeding, slept for longer, needed less night time feeds, had longer night time feeding intervals and day time feeds (St James-Roberts et al., 2017). When employing the criteria of sleeping for a period of greater than 5 hours, it was also reported that infants whose parents used a short delay before feeding at 2 and 5 weeks of age were approximately twice as likely to meet the criteria of sleeping for a period of 5 hours or greater without waking at 3 months of age (St James-Roberts et al., 2017).

Effect of removing parental intervention. The strength of the relationship between parental behaviour and infant sleep is further demonstrated by behavioural sleep interventions for infants, which often focus on altering parent behaviour to shape infant sleep (Sadeh et al., 2007). These interventions operate on the premise that by decreasing excessive parental involvement, infants' capacities to develop self-soothing skills will increase and therefore

lead to better sleep (Sadeh et al., 2007). While not demonstrating a causal link between parental behaviour and infant sleep difficulties, the success of extinction based procedures which promote the reduction of parental attention to infants during the bed time routine and night waking demonstrate the profound affect that altering parental involvement during sleep routines has on infant sleep.

In their study, France and Blampied (2005) evaluated several procedures which are designed to alter infant sleep. They included unmodified extinction (systematic ignoring) alongside two modifications, systematic ignoring with minimal parental check and systematic ignoring with parent presence in their study with infants aged between 6 to 15 months. Infant sleep was tracked using parent reported sleep diaries and night time-lapse infrared video recordings. Measures included frequency of night wakings and duration of crying per night. In response to their infants crying during initial settling or after night wakings parents in the systematic ignoring group were told not to attend to their infants unless the infant was ill or in danger. The minimal check group was told to put their infant to bed and to respond to crying on a ten-minute schedule but were not to stay in the room for more than 1 or 2 minutes. Parents in the parental presence group were instructed to put their infants into bed, bid good night and then lie down in the infant's room on a separate mattress and feign sleep for a period of 7 nights. Parents in the parental presence group were also told not to attend to the infant directly while they were in the room.

Findings of France and Blampied (2005) revealed that all three methods of treating infant sleep resulted in a decrease in night wakings, demonstrating that withdrawal of excessive parental involvement during the initial settling period and after subsequent night wakings results in a significant improvement in infant sleep when measured by signalled night wakings. The difference between the speed of decrease in night wakings between

systematic ignoring group and minimal check group in particular demonstrates the clear association between parental involvement and infant sleep problems such as night wakings, with the unmodified group, which demanded complete withdrawal of parental attention resulting in one of the fastest decreases in infant night wakings when compared with other methods which had varying levels of parent child interactions.

Parental cognitions and beliefs. It has been established there is a clear association between parental nocturnal caregiving behaviour and infant sleep. In order to further investigate what motivates parents to adopt certain caregiving behaviours or strategies Tikotzky and Sadeh (2009) examined the role of maternal cognitions regarding sleep and the association that occurs between maternal cognitions, infant soothing behaviours and infant sleep quality. Tikotzky and Sadeh (2009) followed mothers from pregnancy through to when their infants were 12 months old, and employed multiple measures to assess maternal cognitions, infant sleep and maternal comforting behaviours. Measures included a mixture of questionnaires and hypothetical situations to measure maternal cognitions and infant sleep. In their study, maternal cognitions during pregnancy were found to be associated with infant sleep quality at 6 and 12 months of age. In particular, maternal cognitions that emphasised infant distress and need for assistance soothing predicted a higher number of night wakings at 6 months of age where as maternal cognitions that stressed limit setting were associated with more consolidated sleep. This association was found to extend into the first year of life with maternal cognitions at 6 months of age also predicting number of night wakings at 12 months of age. The results of Tikotzky and Sadeh (2009) are consistent with the results of Zaidman-Zait and Hall (2015) who also found an association between low parental belief in ability to use behaviour to influence their infant and more disturbed infant sleep, as well as an association between high reports of maternal overprotectiveness and more disturbed infant sleep.

As discussed previously parental involvement and caregiving behaviours have been found to be consistently associated with infant sleep (Adair et al., 1991; Anders et al., 1992; Burnham et al., 2002; DeLeon & Karraker, 2007; Morrell & Cortina-Borja, 2002; Touchette et al., 2005). Therefore, in their study Tikotzky and Sadeh (2009) hypothesised that parental soothing behaviours would mediate the relationship between maternal cognitions and infant sleep. Analysis of the relationship between maternal cognitions and infant sleep found that higher ratings on the distress scale were associated with and predicted more parental involvement in soothing. Increased ratings on the limit scale were found to be associated with and predict less parental involvement and higher rates of infant self-soothing. Furthermore, results confirmed that concomitant links were found between parental soothing behaviour and infant sleep at both 6 and 12 months of age, with increased parental involvement at night-time predicting higher rates of parent reported night wakings at 12 months of age.

Parental tolerance to crying. Sadeh et al. (2016) investigated whether parental tolerance to crying may also play a role in contributing to when and how parents respond to their infants at night time. Sadeh et al. (2016) assessed parental tolerance to crying across three groups of participants: parents of sleep-disturbed infants, parents of infants without sleep problems and childless married couples. The construct of tolerance to cry was assessed by employing multiple methods such as questionnaires and hypothetical situations. Some of the measures required participants to be presented with audio and video clips of infants crying. As hypothesised by Sadeh et al. (2016) parents in the clinical group demonstrated shorter intervention delays compared to parents without sleep disturbed children. In other words, parents of the sleep disturbed infants were quicker than parents with non sleep disturbed infants to indicate they would like to intervene and respond to the crying infant when viewing the vignette, therefore suggesting a lower tolerance to cry. The authors noted this as being a particularly significant result considering the context of the scenario in which

parents indicated their desire to intervene. The video scenario featured a non-familiar infant during a daytime period of wakefulness.

Kangaroo Care Research.

As described above, there has been a significant amount of research which has investigated the effect of parental behaviour on infant sleep. Another area of research which examines the effect that parental practices can have on infant sleep is research on Kangaroo Care practices. Kangaroo Care, was initially developed by Edgar Rey in Bogota, Colombia in the 1980's as an alternative treatment to standard in-hospital care for low-birth weight infants who were otherwise stable (Charpak et al., 2005; Charpak & Ruiz, 2016; Feldman, Weller, Sirota, & Eidelman, 2002). It continues to be among the top treatments of choice in many developing countries due to its availability and its ability to reduce reliance on expensive and scarce resources such as incubators. Kangaroo care also became a method of choice throughout the United States and Europe when it began permeating industrialized countries in the early 1990's (Feldman, 2004) and has since been described as humanizing neonatal care in developed nations (Charpak & Ruiz, 2016)

Kangaroo care consists of the parent, typically the mother, engaging in the kangaroo position with their infant. The kangaroo position is achieved by the mother holding the infant in a vertical position between her breasts and under her clothes, mimicking that of a marsupial. The skin to skin contact which is achieved by this position is the key element of kangaroo care. The kangaroo position can be employed continuously or intermittently. (Charpak et al., 2005). In resource-rich countries, kangaroo care is seen as complementary to incubator care and as a result continuous kangaroo care is rare. Instead the kangaroo position is adopted intermittently (Campbell-Yeo, Disher, Benoit, & Johnston, 2015). The focus of the kangaroo position and subsequent skin to skin contact (SSC) in developed countries differs

slightly from that of developing countries. The main aim of kangaroo care in developing nations is to regulate body temperature, heart rate, oxygenation and to encourage feeding. In developed countries however the focus of kangaroo care has been placed upon promoting early bonding between the infant and their caregiver and encouraging breastfeeding (Campbell-Yeo et al., 2015).

There has been a significant amount of research evaluating kangaroo care and its effect on a multitude of variables with pre-term infants. These variables include: mortality, body temperature, infection, breast-feeding, growth, length of hospital stay, emotional regulation, reactivity, arousal modulation, mother-infant shared attention, infant sustained exploration, sleep distribution, sleep-wake cyclicity, (Cattaneo et al., 1998; Charpak, Ruiz-Pelaez, Figueroa de C, & Charpak, 1997; Feldman et al., 2002).

Kangaroo care and sleep with premature infants. A number of studies have reported a relationship between kangaroo care or skin to skin contact and more organised sleep for premature infants (Feldman & Eidelman, 2003; Feldman et al., 2002; Ludington-Hoe et al., 2006; Scher et al., 2009). Three out of the four studies included in this review utilised a pre-test/post-test design with an intervention group and control group (Feldman & Eidelman, 2003; Feldman et al., 2002; Ludington-Hoe et al., 2006). Randomisation was employed where possible but in some cases matched controls were included (Feldman et al., 2002). Of these 3 studies, 2 studies used behavioural observations as their main measure and 1 study used EEG and polysomnography to assess infant sleep. All studies reported that the premature infants who experienced kangaroo care showed more mature sleep patterns as demonstrated by more time spent in quiet sleep and wakefulness and less time spent in active sleep than premature infants who did not receive kangaroo care (Feldman & Eidelman, 2003; Feldman et al., 2002; Ludington-Hoe et al., 2006). Kangaroo care was administered for at

least 1 hour a day over 14 days in two studies (Feldman & Eidelman, 2003; Feldman et al., 2002) and for one 2-3 hour block in one study (Ludington-Hoe et al., 2006).

Scher et al. (2009) also examined the effects of kangaroo care on infant sleep. However, in their study, in addition to including a control group of premature infants who did not receive kangaroo care, Scher et al. (2009) also included a group of full term infants, who were observed 1-3 days after delivery. To assess infant sleep Scher et al. (2009) employed electroencephalographic (EEG) and polygraphic measures in combination with some visual and video observation. The results of their study were consistent with those previously reported by Ludington-Hoe et al. (2006), Feldman et al. (2002) and Feldman and Eidelman (2003), concluding that premature infants who experienced skin to skin contact over an 8 week period, demonstrated an increase in time spent in quiet sleep and fewer rapid eye movements (REMs) when compared to premature infants who did not receive kangaroo care. However, furthering the results of those previously mentioned, Scher et al. (2009) reported that the premature infants who received kangaroo care also spent more time in quiet sleep, had longer sleep cycles and fewer rapid eye moments when compared with the full term infants.

Extending the results of the previously mentioned studies, Feldman, Rosenthal, and Eidelman (2014) conducted a longitudinal study which investigated the effects of kangaroo care for premature infants 10 years after the intervention. In the study which featured 146 mother infant dyads, the authors measured multiple variables including; autonomic functioning, sleep organisation, parental mental health, mother-child interaction and cognitive development. For the purpose of this review however, there will be a focus upon the findings relating to kangaroo care and infant sleep. The kangaroo care intervention consisted of 1 hour of kangaroo care per day for 14 days. The infants were aged between 25

and 34 gestational weeks during intervention. The control group was a matched control group from a nearby hospital in which kangaroo care had not yet been introduced as standard care. Sleep organisation at term age was measured by sleep wake cyclicity computed from visual coding using the Blackman-Tukey analysis and results showed intervention infants had more organised sleep than control infants. At 10 years of age, sleep was measured by actigraphy and results of the study revealed children in the intervention group had greater sleep efficiency, defined as proportion of true sleep out of total time in bed, when compared with the children who did not experience kangaroo care as premature infants.

Kangaroo care and sleep with full term infants. Ferber and Makhoul (2004) also investigated the effects of kangaroo care on infant sleep, however their sample included only full term infants. Using randomisation Ferber and Makhoul (2004) created two groups, an intervention group and control group and observed the effect of a 1 hour session of kangaroo care shortly after birth on neurobehavioral responses, namely infant sleep and physical movements. Following delivery infants in both groups were initially placed on their mother's chests while their umbilical cords were cut and then removed for approximately 15 minutes to be dried, weighed and dressed. Following this, infants either began intervention or were returned to the nursery. Infants in both groups were both observed 4 hours after delivery for a period of one hour while in the nursery using a behavioural recording tool adapted from the Naturalistic Behavioural Observation of the Newborn Infant. Results showed that the infants who had experienced the one hour of kangaroo care spent more time in sleep states and less time in transitional, fussy, crying and alert states when compared to the infants who only experienced 5-10 minutes of kangaroo care. Furthermore, the infants who had experienced the hour of kangaroo care, spent more time in quiet sleep than infants who had only experienced 5-10 minutes of kangaroo care. The results also showed that those infants who had experienced the 1 hour of kangaroo care demonstrated more flexed and less extended

movements when compared to the infants who did not have the 1 hour of kangaroo care. From their results, Ferber and Makhoul (2004) propose that maternal touch such as in kangaroo care helps encourage better central nervous system control as demonstrated by more time spent in quiet sleep and more flexed and less extended movements.

Environmental Noise and Sleep. Many studies have examined the effect of environmental sounds and noises on infant sleep (Brackbill, 1970; Brackbill, 1975; Brackbill et al., 1966; Detterman, 1978; Forquer & Johnson, 2005). These include the effect of the heartbeat sound, the sound of white noise machines and other sounds including the sound of metronomes and lullabies (Brackbill, 1970; Brackbill et al., 1966; Detterman, 1978; Forquer & Johnson, 2005).

Heartbeat sound and sleep. Studies have investigated the effect of the human heartbeat sound on several aspects of infant functioning including weight gain (Palmqvist, 1975), activity levels (Roberts & Campbell, 1967) crying, (Detterman, 1978) heart rate (Schmidt et al., 1980; Schön & Silvé, 2007) motor responses (Schmidt et al., 1980) and sleep (Schmidt et al., 1980). For the purpose of this review however the following discussion will include a more detailed description on research documenting the effect of heartbeat sound on infant crying and sleep only.

Research examining the effect of the heartbeat sound on the behaviour of infants began over 50 years ago in the 1960's with experiments conducted by Salk in 1960, 1961 and 1962 (as cited in Detterman, 1978). It is reported that Salk concluded from his experiments that infants who were exposed to a recording of a heartbeat sound at 85db had lower rates of crying as a group when compared to a group of infants who were not presented with the recording (as cited in Brackbill et al., 1966; Detterman, 1978). In addition, it has been reported that Salk also presented that the infants in the heartbeat group were observed to gain

more weight when compared to no heartbeat group infants despite there being no significant difference in food intake between groups (Schön & Silvén, 2007). It is said that from these results, Salk proposed that the increase in weight gain was the result of the decrease in crying and restlessness and therefore the heartbeat sound may serve to aid infants adjust better to extra uterine life (Tulloch et al., 1964). The reliability of Salk's results have since been contested due to several methodological flaws in his experiments such as inconsistent information regarding procedures, significant discrepancy between control and experimental group numbers and inappropriate data collection and analysis strategies (Detterman, 1978). It was also noted that the nurseries in which Salk conducted his research were under the flight path of a nearby airport and therefore Salk's results may be explained as the heartbeat sound providing a screening effect against associated noises for the infants in the heartbeat group (Tulloch et al., 1964). In addition to his research with infants, Salk is reported to have also researched the effect of heartbeat sound and other sounds such as lullabies with 2 year old children (as cited in Brackbill et al., 1966). It is reported that Salk described that when compared with either the sound of a metronome ticking or lullabies the sleep latency of children was halved when exposed to the sound of a heartbeat (as cited in Brackbill et al., 1966).

In order to clarify the reliability of Salk's findings, several studies have conducted similar experiments examining the effects of the heartbeat sound on infant functioning (Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964).

Tulloch et al. (1964) conducted a replication of Salk's work (Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) and also investigated the effect of heartbeat sound on weight gain, activity level and food intake in a study with very similar properties to the experiments Salk conducted with infants (as cited in Brackbill et al., 1966; Detterman, 1978;

Tulloch et al., 1964). In contrast to Salk however, Tulloch et al. (1964) presented the heartbeat sound at 45db, compared to 85db used by Salk. To measure the effect of the heartbeat sound on infant state, researchers assessed each infant for 15-20 seconds, 6 times a day and assigned one of the following states, asleep, awake but not moving, moving moderately, moving actively, crying fussing, crying moderate and crying frantic. Like Salk (as cited in Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) Tulloch et al. (1964) also used an audio recorder to assess rates of crying in the group. The recorder was turned on for 4, 5 minute periods daily and subsequently coded for percentage of time one or more infants were crying during the recorded sessions. Contrary to Salk, (as cited in Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) Tulloch et al. (1964) did not report any effect of heartbeat sound on state, weight gain or food intake. The significant reduction in the intensity of the heartbeat sound by Tulloch et al. (1964) may explain the absence of an effect in this experiment. The measure of activity was also reported to be developed for the study and therefore it may be that this was not a valid or reliable measure of infant state given its brevity.

Brackbill et al. (1966) also aimed to replicate the findings of Salk (as cited in Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) and reported on two experiments in their 1966 publication. Their first experiment described featured preschool children who were exposed to a range of sound conditions such as heartbeat sound, lullabies, metronome and no sound. Using a latin square design, Brackbill et al. (1966) compared sleep latency with pre-schoolers over 4 nursery schools who were exposed to either heartbeat sound, no sound, metronome or lullaby during their daily one hour nap period. Each condition was employed once a day for a week over 4 weeks. Results revealed a significant difference in sleep latency between the no sound condition and all sound conditions. Contrary to hypotheses however there was no significant difference in sleep latency between heartbeat

sound and other sounds (Brackbill et al., 1966). While this experiment does not demonstrate that the heartbeat sound in particular aids infant sleep, it does suggest that noise in general decreases sleep latency for young children. In this particular study where the participants were sleeping in close proximity to one another, it could be likely that the noise acted as a screen or cover for other noises which may have been interfering with the participants ability to fall asleep. This is similar to the conditions under which Salk (as cited in Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) conducted his experiments.

In the second study described in their publication, Brackbill et al. (1966) also presented four modes of sound, but instead to infants with an average age of 48 hours. Individually each infant was presented with either, heartbeat sound, lullabies, metronome or no sound for 15 minutes at a time. During this time crying, motor activity, heart rate and regularity of respiration were all measured. Similar to experiment 1, crying was found to reduce under all sound conditions when compared to the no sound condition, however there was no significant difference between the heartbeat condition and the other sound conditions. The same results were found for heart rate, with heart rate being significantly higher and irregular in the no sound condition compared to the sound condition, but no significant difference between the sound conditions. Respiration was also more regular under sound conditions but there was no effect found between the sound conditions. There was no significant difference for motor activity between any of the conditions.

In a further replication of Salk's experiment (as cited in Brackbill et al., 1966; Detterman, 1978; Tulloch et al., 1964) Detterman (1978) examined the effect of heartbeat sound on crying in infants aged between 48 and 96 hours of age using both an experimental and control group. In the study a wooden box was mounted onto the infants' bassinet and this was used to play a heartbeat sound as well as record the infant's crying. The heartbeat sound

was played whenever the infants were in the bassinet at an intensity of 85db. Consistent with the results of Tulloch et al. (1964), Detterman (1978) also did not detect a difference in rates of crying between the group of infants exposed to the heartbeat sound and those infants who were not.

Whilst the results of Detterman (1978) and Tulloch et al. (1964) do not suggest that heartbeat sound plays a significant role in reducing infant crying, the results of Brackbill et al. (1966) indicate that noise, including that of heartbeat sound, may be associated with pacifying effects for infants and young children.

White noise and sleep. Following her previous work with noise and infant functioning as described above, Brackbill (1970) investigated the effect of auditory stimulation, produced by a noise generator at 85db on infant state, respiration, heart rate, motor activity and evoke response. 18 full term infants with a median age of 30 days were exposed to three conditions of noise, no sound, intermittent sound and continuous sound. Each condition lasted 8 minutes and infants were assigned to one of six possible orders of the conditions. Results showed that level of arousal decreased when the sound was generated continuously and increased during the intermittent sound condition, as compared to the no sound condition. After establishing the promising effects of continuous white noise on infant function, Brackbill (1975) examined the effects of varying intensity of white noise on infant arousal levels. Brackbill (1975) observed 90 full term infants with a median age of 44 hours during a control period in which ambient noise level was at 55db, and during 3 experimental periods during which the noise was produced at 60, 70 and 80db. Measures included infant state and heart rate. The control period lasted for 30 minutes and the experimental period lasted 30 minutes. The striking result of the study was that related to quiet sleep. The amount

of time infants spent in quiet sleep increased from 12.9% of the time in the control period to 67.9% of the time under the 80db condition.

Given these findings, several other studies have also investigated the effect of white noise with a range of other populations (Forquer & Johnson, 2005; Spencer, Moran, Lee, & Talbert, 1990). These are discussed below.

Spencer et al. (1990) examined the effect of white noise on the sleep of 20 infants aged between 2 and 7 days old. Infants were randomly assigned to two groups: a white noise group and no white noise group. Following allocation to their group, infants were observed for 5 minutes, either with or without white noise playing. It was observed that 80% of the infants who had the white noise playing fell asleep within the first 4 ½ minutes of the observation. In comparison, 25% of the infants in the no white noise group fell asleep in the five minutes observation time. Of the babies who had not fallen asleep by the end of the five minute observation in the no white noise group, 73% fell asleep in the next five minutes once the white noise had been turned on. Whilst this study suggests white noise significantly decreases sleep latency for infants, there was no information provided about the context in which the experiment was provided. Other factors which may have influenced how quickly an infant fell asleep such as time of last feeding or sleep was not provided and therefore the effects of these variables cannot be discounted.

Forquer and Johnson (2005) also examined the effects of white noise on sleep but with children aged between 13 and 23 months. Using a non-concurrent multiple baseline design, Forquer and Johnson (2005) instructed parents to play the white noise at 75db for all sleep times including naps and overnight for their children whilst employing their regular bedtime routine. Sleep diaries completed by the parents showed improvements in either night

wakings or sleep latency. Whilst 2 out of 3 participants showed a decrease in night wakings, one participant experienced a return to baseline levels in follow up.

Breathing Bear Research

The effect of an artificial breathing sound on the sleep of premature infants can be observed in research which features the ‘breathing bear’ (Ingersoll & Thoman, 1994; Thoman & Graham, 1986; Thoman, Hammond, Affleck, & Desilva, 1995; Thoman, Ingersoll, & Acebo, 1991). Research has also evaluated the breathing bear’s effect on unsettled full term infants (Novosad & Thoman, 2003). The breathing bear was designed as a source of stimulation for premature infants to aid neurobehavioural maturation while premature infants were hospitalised (Thoman & Graham, 1986). The breathing bear featured in a series of studies was a soft toy bear made of dyed blue sheepskin that was made to breathe using an external pump. The breathing rate of the bear was adjustable and was set at one half of the infant’s own respiration rate during quiet sleep (Thoman & Graham, 1986).

Breathing bear and sleep. Multiple studies have found increased rates of quiet sleep among premature infants who were exposed to the breathing bear for 3 weeks while hospitalised when compared to premature infants who were exposed to a non-breathing bear, indicating a more mature sleep pattern (Ingersoll & Thoman, 1994; Thoman & Graham, 1986; Thoman et al., 1995; Thoman et al., 1991). However, among the studies there is significant variance in terms of when this effect can be detected. Thoman and Graham (1986) and Thoman et al. (1995) both detected an increase in quiet sleep among premature infants who had been exposed to the breathing bear during the preterm period. Both studies introduced the breathing bear and non-breathing bears to infants aged between 32 and 33 weeks conceptional age and detected a difference in the amount of quiet sleep between groups at 35 weeks conceptional age. Thoman et al. (1991) and Ingersoll and Thoman (1994)

however did not detect any differences in sleep state distribution between premature infants who had the breathing bear and premature infants who did not have a breathing bear during the preterm period but did detect a difference at 41, 42, 43, 44 and 45 weeks conceptional age, during the post term period. These later studies were the only studies to follow infants post discharge from hospital and indicate that the effects of the intervention are observable beyond the intervention period.

While several factors may have contributed to the lack of an effect during the preterm period in the studies by Thoman et al. (1991) and Ingersoll and Thoman (1994), the authors believed that the advances in medical technology and nursing strategies that occurred between Thoman and Graham's 1986 study and the subsequent studies in 1991 and 1994 is the most likely explanation for the non effect. However this is not supported by the finding of Thoman et al. (1995) who did detect a difference during the preterm period.

Breathing bear research and infant crying. Researchers have also evaluated the effects of the breathing bear on unsettled behaviour and temperament in full term infants (Novosad & Thoman, 2003). 35 full term infants were provided with either a breathing bear or non breathing bear from 5 weeks of age to 6 months of age. The study measured the effect of the bears on infant crying time, infant temperament and maternal stress and depression. Contrary to the authors' hypothesis, results showed no difference in mother reported crying time between groups. Interestingly, the results did however report an effect for mothers negativity ratings and stress and depression scores, with mothers in the breathing bear group rating their infants less negatively and having lower scores on the Parenting Stress Index and Beck Depression Inventory when compared to mothers in the non-breathing bear group (Novosad & Thoman, 2003). Whilst the intervention did not provide the results the authors were expecting, the bear seems to have had a positive impact on the maternal mental health

measures and mothers' assessment of infant temperament without reducing maternal reported cry time. To account for the surprising findings, the authors suggest two mechanisms by which the bear may have altered the mothers' experiences of their infants. Firstly, they propose that the bear was reassuring for the mothers. It may have been that the parents expected the breathing bear to be soothing and comforting for their infants and therefore believed that their infants were acting differently than they would have been had they had a non-breathing bear. Secondly, the authors suggest that changes in the infants that did potentially occur were not reflected by the chosen measure of maternal reports of crying time. For example, they suggest that while total crying time may not have changed, other aspects such as intensity, duration of bouts, or diurnal distribution of crying may have been altered and therefore this aspect mediated the relationship between the bear and the outcome variables but was not captured in the measures used in the study (Novosad & Thoman, 2003).

In conclusion, there is significant evidence that many environmental factors influence the development of infant sleep-wake patterns (Morrell & Cortina-Borja, 2002; Sadeh & Anders, 1993; Thoman & Graham, 1986). While the evidence is scarce for the effectiveness of the heartbeat sound in particular on infant sleep, research does suggest that white noise, in a variety of forms, may be effective for decreasing sleep latency (Spencer et al., 1990), reducing night wakings (Forquer & Johnson, 2005) and increasing the percent of quiet sleep (Brackbill, 1975). The majority of the work reviewed above however, features participants of either a very young age, or infants born prematurely. Another common aspect of the relevant literature reviewed is the setting. Most of the research discussed has been undertaken in either hospitals or laboratories. These points both reduce the applicability of these studies to a wide range of infants. In order to investigate the effectiveness of white noise on infant sleep in a more varied population further research is required.

Aims of the Study

The aim of this research study is to investigate the effectiveness of the Lulla Doll, a heart beating breathing doll, on infant sleep in a sample of infants aged between 4 and 8 months of age in the home setting. The Lulla Doll is marketed as a tool which helps infants sleep longer, as a result of the 8-hour recording of a heartbeat and breathing sound that the doll plays.

Following its release onto the market, the use of the Lulla Doll has been observed to be significantly popular with parents who wish to improve their infants sleep. Despite it's popularity, currently there is no empirical evidence which substantiates the claim that the doll does improve infant sleep. Whilst there is significant research which evaluates other forms of white noise on infant sleep, this body of research cannot be generalised to use of a heart beating breathing doll specifically. Kangaroo care research also suggests a relationship between parental closeness and improved infant sleep, however it has also not yet been established if the lulla doll is effective in mimicking parental closeness closely enough to alter infant sleep. This study therefore aims to evaluate the effectiveness of a heartbeating breathing doll on improving infant sleep, using a sample of 5, 4 to 8 month old infants. In order to track any potential changes to infant sleep from use of the doll, videosomnography and sleep diaries will be used to track infants sleep before and during the use of the doll.

There are two research questions for this study.

1. Does a heart beating breathing doll have any effect on aspects of infant sleep as experienced by the infant's parents?
2. Does a heart beating breathing doll show any effect on sleep state organisation?

Chapter Two

Method

Participants and Recruitment

Participants were 5 healthy, typically developing infants aged between 4 and 8 months of age. All participants were recruited through online advertisements which were posted on social media. Further information regarding the participants is included in Table 1. The researcher initially posted the recruitment poster (Appendix A) on Facebook, including on local suburb community pages and her own Facebook profile. The advertisement was also posted upon other Facebook pages such as on local parenting pages by acquaintances of the researcher and on the personal pages of the researcher's acquaintances. The advertisement called for families who were planning on using a doll but had not done so, and who were interested in participating in a study, to contact the researcher via email or phone. Numerous people also contacted the researcher directly on Facebook. A \$50.00 remuneration was offered for participation in the study. A limited number of dolls were also offered as available for loan and an opportunity to purchase these on completion of the study was offered.

At first, after the researcher received contact from potential participants she sent them information sheets (Appendix B) with an invitation to contact the researcher if they were interested in proceeding. Upon hearing back from the participant the researcher would then confirm the participant's eligibility and arrange to meet to discuss beginning the study. However, as the recruitment phase progressed the researcher began to make contact with the family to confirm eligibility before providing information sheets as it became apparent that many families were not meeting the eligibility criteria. This change in procedure was done to ensure that families were not disappointed after being provided with more information. The

initial eligibility criteria were as follows: (a) at least one English speaking parent; (b) infant must sleep separately from parents; (c) healthy, typically developing infant and aged under 12 months of age (d) the family must reside in the Canterbury area. Initially there was no criteria included that infants must have a sleep problem as it was assumed that only parents whose infants are experiencing some sleep difficulties would respond to the advert, however it became apparent that the advertisement attracted parents whose infants had a wide range of sleep difficulties and therefore additional criteria of infants having difficulty with either settling to sleep or night wakings but were used to sleeping in their own cot was added.

It also became apparent that parents were wishing to use the dolls in a variety of ways, some of which were not compatible with the study design. The inclusion criteria was therefore extended to include the criteria that infants must currently be sleeping the majority of the night in their in own cot. This was necessary to ensure that apart from the addition of the doll into the sleep routine, the majority of the variables in the infant's sleep routine were kept the same, therefore eliminating the influence of other potential confounding variables. This meant that parents who were currently co-sleeping and wanted to transition the infant into their own cot were not able to participate in the study.

Table 1: *Participant information*

	Kelly	Matt	Beth	Char	Oliver
Age at baseline	5m 3 d	5m 6 d	6m 15d	7m 27d	4m 0d
Male/Female	Female	Male	Female	Female	Male
Sleeping location at baseline	Own room	Own room	Parents room	Parents room	Own room
Current sleep management strategies	Breast feed Rock	Breast feed Rock Swaddle Co-sleep	Breast feed Bottle feed Cuddle Co-sleep	Breast feed Bottle feed Rock	Breast feed Bottle feed Rock
Previous relevant sleep management Strategies	White noise	Lullabies	None noted	Sleep training	Shusher (white noise emitting device)
Sleep problem (as defined by parent)	Night waking	Night waking Self- settling	Night waking Self-settling	Night waking	Night waking Self-settling

Ethics

Ethical approval for the study was granted by the University of Canterbury Human Ethics Committee (Appendix C). All participants provided informed consent (see Appendix D and E) to participate in the study after reading an information sheet detailing the requirements of the study and any potential risks. The participants' parents also met with the researcher prior to signing the consent form. During the meeting parents were provided with the opportunity to ask any questions prior to signing the consent form. Confidentiality was also explained to the participants' families during the meeting.

Settings

The research was conducted within the participant's own home. Four out of the five participants remained sleeping in the same place throughout the study.

Apparatus

Camera. To record the participants during the night time period a D-Link DCS-2132L Indoor Cloud IP Camera was used. The camera recorded both visual and audio data. On most occasions it was secured to a wall near the infant's cot using 3M paint tape. For one participant the cot was surrounded by windows so instead the camera was firstly attached to the top of the cot and then secured to the curtains with pins. At all times the location of the camera was agreed on by the parents. The camera was then programmed by the researcher to record for a 12-hour period for 3 nights in a row. The 12-hour period was negotiated with the family to best fit the routine of the infant. Data was recorded on to a micro SD card which slotted into the camera. Parents were not required to do anything to operate the camera except to remove the SD card or to unplug the camera to ensure that it did not continue to record when it was not required. The researcher would return to the families' home to download the data and reset the camera between the recording periods.

Lulla Doll. The Lulla Doll by RoRo is a soft toy with a plastic sound box inserted inside. The sound box is battery operated and once turned on, plays the recording of a heartbeat and breathing sound for 8 hours at 65db. The outer layer of the doll is made of a cotton blend and depicts gender neutral facial features. (Lulladoll.com, 2016).

Measures

Measures in the study were collected from both videosomnography and parent reported sleep diaries. A brief initial interview and an exit interview were also conducted.

Videosomnography. Videosomnography was selected as the method to monitor any changes in sleep state organisation. The videosomnography footage was viewed by the researcher on her laptop at 8 times speed to determine multiple aspects of sleep. From the footage, sleep states and several other variables were noted using a coding system adapted

from (Anders & Keener, 1985). The researcher was trained in the coding system by her supervisor who had previously been trained in the system, by Anders. To determine each sleep state, the infant was observed for any body movements. To begin a period of active sleep, two movements within 3 minutes of each other were required, followed by a third movement within 5 minutes of the second movement (Anders & Keener, 1985). Quiet sleep was defined as a period of at least 5 minutes with the maximum of 1 movement. Each quiet or active sleep period must be sustained for at least five minutes, unless it is prior to or directly after an awakening in which it may be shorter (Anders & Keener, 1985). Awake was scored on a minute by minute basis and was represented by alertness, voluntary movements and open eyes. Each coding state is briefly described Table 2.

From the videosomnography data the following variables were calculated: the amount of time the infant spent in quiet sleep and active sleep, number of signalled and non-signalled wakes, number of sleep state transitions, the number of active to quiet sleep transitions before wake, longest sleep period, time spent out of cot, number of parental interventions, the duration of parental interventions, and the time from which an infant signalled to their parents, for example by crying out, until the time the parent responded. A definition of each variable can be seen in Table 3.

A minimum of 9 nights of VSG data were collected, 3 nights in baseline, 3 nights during the intervention phase and 3 nights during follow up. Due to time constraints and the time intensive nature of coding the videos, only nights 2 and 3 from each phase were coded for data analysis. Extra nights of VSG data were collected in negotiation with the families throughout each phase, in the case of technical difficulties, however not all recordings were used for data analysis.

Table 2: Sleep Wake State Criteria for Assessing Infant Sleep

Code	Criteria
Active Sleep	Active sleep is identified by the presence of frequent body movements such as twitches, sighs and brief cries (Anders & Keener, 1985).
Quiet Sleep	Quiet sleep is represented by the absence of body movement or only occasional body movements (Anders & Keener, 1985).
Awake	Awake is observed as eyes open and alert. The infant may be quiet, talking, crying, lying still or moving about for Awake to be coded (Anders & Keener, 1985).
Parental Intervention	Parental intervention is coded whenever parental intervention is occurring with the infant. This can include soothing through rocking, tucking in, swaddling or any other behaviour a parent performs with the infant whilst the infant is in the cot. (Anders & Keener, 1985).
Out of Cot (OOC)	The out of cot code is used to record anytime the infant has been removed from the cot for any reason. This can include soothing, feeding, changing or other reasons (Anders & Keener, 1985).

Table 3: *Definition of variables derived from videosomnography data.*

Variable	Definition
Percent of quiet sleep	Percent of total sleep time spent in quiet sleep. This was calculated by dividing the number of minutes spent in quiet sleep by the number of minutes spent in active and quiet sleep combined and multiplying by 100.
Number of sleep state transitions	Number of transitions per night, including from active sleep to quiet sleep and quiet sleep to active sleep
Number of active to quiet sleep transitions before a wake	Largest number of active to quiet sleep transitions before a wake in a night
Longest sleep period	The longest period of uninterrupted sleep maintained by the infant. This is calculated as the time between sleep onset and time of wake (including signalled and unsignalled wakes)
Response delay	The time between when an infant signals and the parent responds
Sleep efficiency	The percentage of available time (time in bed) that is spent asleep. Available time is defined as any time the infant is in the cot, they may be awake or asleep.
Wake duration	The amount of time spent in the cot and awake
Out of cot	Any time the infant is not in the cot between the time they have been initially put into bed and the time they are up for the day

Parent report sleep diaries. Parent report sleep diaries from the Canterbury Sleep Programme (Appendix F) were used to collect nightly information regarding the infants' sleep. Information collected included time, location and length of day-time sleep, time of night bedtime, time to silence from initial placing in bed, timing and duration of night waking and parent and infant actions during these times. Parents completed the diaries for the

duration of baseline, intervention and follow up. Parents were relieved of completing diaries between intervention and follow up for one month.

Interviews. Two brief interviews were held with the participants' parents. For four out of five participants only the mothers of the infants were present and for the fifth participant both the mother and father were present at both interviews. The interview structures for both the initial interview and exit interview are detailed in Table 4 and 5. In addition to the questions listed below about aspirations for the dolls use and screening for problems which might contra-indicate its use, confidentiality and consent (Appendix C) were also covered with participant's families at the initial interview.

Table 4: *Initial interview questions*

Questions
1. Tell me about wanting to use the Lulla Doll
2. What have you tried before? Tell me about that
3. Tell me about a typical night for your infant
4. What has it been like in your child's life? – Have there been any ups/downs or changes in your infants life?
5. Do you have any other worries or concerns within the family at the moment?

Table 5: *Exit interview questions*

Questions
1. Tell me about using the Lulla Doll – how did it go?
2. Tell me about any changes you may have noticed
3. Will you continue to use the doll?
4. Would you use it again in the future with another child?
5. Is there anything else you are thinking about trying with your infant?

Design

This study uses a within participant, multiple baseline, across participant design. A within participant design has been selected as it is a rigorous method for evaluating the effects of intervention (Vannest & Ninci, 2015). Within participant designs use participants as their own control group, comparing behaviour change across different phases with varying conditions applied (Lenz, 2015). They employ replication in order to draw causal inferences (Lenz, 2015). A benefit of these designs is they allow for individual differences (Plavnick & Ferreri, 2013) and therefore are more tolerant of flexibility whilst maintaining scientific rigour (Lenz, 2015). Multiple baseline has been selected as it is a rigorous approach that is suitable for when withdrawal is not achievable, either due to behaviour being unlikely to return to pre intervention levels, or withdrawal being ethically inappropriate (Morgan & Morgan, 2009). Multiple baseline involves a single transition from baseline to intervention across multiple participants, behaviours or settings, however this transition is staggered across subjects to occur at different times to rule out possible interference from other variables (Morgan & Morgan, 2009).

Procedure

This study was comprised of three phases: baseline, intervention and follow-up.

Baseline. All participants began the study in the baseline phase. Length of baseline was randomly allocated as 5, 10 or 15 days for all participants except for one, using an online number generator. Owing to time restraints over the Christmas period, Char was knowingly assigned the shortest baseline of 5 days to fit in with family holiday plans. During baseline, a minimum of 3 or 6 nights of videosomnography data were collected depending on the length of baseline. Whilst only one period was used for final data analysis, multiple sets of

recordings were made during the intervention phase in case of equipment failure. Parental sleep diaries were completed by parents for every night of the baseline period.

Intervention. Following baseline all participants entered a 21-day intervention period in which the doll was introduced to the infant and used during all night time sleep periods. Most parents also chose to use the doll during daytime sleep periods but this occasionally fluctuated owing to preschool attendance by some participants. During this period, multiple 3 night videosomnography recordings were collected. Like in baseline, multiple sets of recordings were made during this phase in case of equipment failure. Parental sleep diaries were also completed by the infants' parents for the duration of the intervention period.

Follow up. The follow up phase began 4 weeks after the commencement of the intervention phase, a total of 7 weeks after the introduction of the doll to the infant. The follow up phase consisted of a week long period. During this period parents completed nightly sleep diaries and 3 nights of videosomnography data was collected. For some participants this phase commenced later than 4 weeks after the conclusion of the intervention phase due to infant illness, equipment failure and family holidays. Parents continued to use the doll for the period between intervention and follow up.

Data Analysis

Data from the parent report sleep diaries was analysed using visual analysis. Three variables were extracted from the diaries: sleep onset delay, the number of wakings and total duration of night waking and graphed onto a time series graph for visual analysis.

For the variables derived from the VSG data, an average from the two nights in each phase was calculated. These averages were then compared against each other and graphed using a modified Brinley plot. To judge any changes after the introduction of the doll, the

average of the two nights in baseline were compared against the average of the two nights in the intervention phase.

Reliability

Videosomnography. To ascertain the reliability of the coding of the VSG data, a portion of the VSG data was also coded by another researcher who was trained in the coding system. Eight of 32 nights was selected by a random number generator. Owing to the large amount of time needed to code entire nights, a randomly selected quarter of each night was selected for coding. Each state change noted by the researcher was marked as either agree or disagree by the other researcher. The number of agreements was then divided by the total number of agreements and disagreements and multiplied by 100 to achieve a percentage of agreement between the two coders.

Sleep Diaries. Reliability of the parent report sleep diaries was ascertained by comparing the nights of sleep diary data with the coded nights of VSG data. The two nights of VSG data coded for each phase was compared against the parent report diaries for the same nights for two variables, sleep onset delay and number of signalled night wakings. Time constraints meant that reliability was not calculated for the third sleep diary variable; duration of night waking. For both sleep onset delay and number of signalled night wakings, each night was marked as an agreement or disagreement. For sleep onset, agreement was indicated if each source was within 15 minutes of each other. The number of night wakings was marked as an agreement if the discrepancy between the source was two or less. The number of agreements was then divided by the total number of agreements and disagreements and multiplied by 100 to achieve a percentage of agreement between the two coders

Chapter Three

Results

This chapter will begin by considering any changes in the variables derived from the parent report diaries: sleep onset delay, number of night wakes and night waking duration. It will then assess any changes in sleep state organisation as captured by videosomnography data. It will finish by discussing the results of the interviews with the parents.

Quality of data.

Kelly. Kelly's data collection was disrupted by two events. A family holiday delayed her follow up recordings by a week. On Night 4 of follow up Kelly hit her head before bed and her parents altered their responses to her and her sleep accordingly. Kelly was also ill on Night 13 with a sore tummy.

Matt. From the 6th day of baseline, Matt's mother swaddled him before bed at night and after night wakings. As a consequence, the researcher was unable to see body movements as closely as in other participants. This is likely to have affected the coding of active sleep and quiet sleep for Matt which rely upon the detection and timing of body movements. So it is possible that his active sleep was underscored. Swaddling did not affect any other variables. Matt had illness on Night 12 of intervention with no apparent effect.

Beth. Beth was ill on Nights 23 and 24. In addition, the follow up phase was a week late owing to a combination of illness and equipment failure. Due to equipment failure in follow up, sleep diaries were collected for an additional week.

Char. During Char's baseline and the intervention phase the camera was by necessity attached to the end of the cot itself and did not capture the entirety of the cot in the frame. This meant that in some periods not all of Char's body was visible. This may have affected scoring. During the break in data collection between intervention phase and follow up phase,

Char's parents decided they would like to resume their sleep training programme as they were not satisfied with the progress of the doll. It was arranged between the researcher and the family to capture one more recording before they began the behavioural sleep intervention.

Follow up 1. The 3-night recording scheduled prior to the behavioural intervention commencing was collected 5 weeks and 1 day after the introduction of the doll intervention period. Sleep diaries were also completed by Char's parents for these three nights. This phase is referred to as 'Follow up 1'.

Behavioural intervention. Char's behavioural sleep intervention which was conducted independently of the research. As the sleep training was a 'top-up' of previous training, Char's parents chose to use a gradual check method. At bedtime, Char's parents would place Char in her cot, lie her down, give her a kiss and a quick touch on the bottom or head and tell her "it is sleep time now". This would be completed within a minute then Char's parents would exit the room. If Char began to cry Char's parents would check her after particular intervals. The first check was completed after 1 minute, the second check after 3 minutes and then checks were completed every 10 minutes until Char fell asleep. At every check the same procedure as above was implemented. No data was collected during this phase.

Follow up 2. A second follow up was arranged with Char's family 4 weeks after her behavioural sleep intervention had commenced. Char's parents collected one-week's worth of sleep diaries and a 3-night video recording was also collected during this phase. This phase is referred to as 'Follow up 2'

Oliver. After three weeks of trialling the doll and continuing to rocking, Oliver's mother was not satisfied with any effect from the doll and expressed interest in withdrawing

her rocking completely. At this point Oliver's mother was offered a sleep programme with the researcher and her supervisor and a behavioural sleep intervention begun. The doll continued to be used in combination with the behavioural intervention.

Behavioural intervention. This phase began with an interview with both Oliver's mother and father. The interview re explored the infant's past sleep history and reviewed all past strategies which had been used or trialled to manage the infant's sleep. The interview also explored the infant's development and health as well as some questions exploring the pregnancy and birth of the infant. During the interview the researcher also discussed the potential intervention, how both parents felt about carrying out the intervention and any potential distress that may be experienced.

After discussing the infant's sleep with the parents, the researcher met with her supervisor and parental presence was selected as the most appropriate intervention for the infant and his parents. A meeting was then set with the parents to discuss the intervention and go over any questions they had. The following instructions were provided to the parents and a suitable night was arranged for the parents to begin the intervention.

“When you put your baby to bed at night, put him into the cot, kiss him goodnight and then lie in the alternate bed in that room pretending to be asleep. Remain like this until your child has settled to sleep. At this point you can quietly leave the room and resume your evening activities. If your baby wakes and cries, return to the room. Do not interact with your baby but go straight to the alternate bed and pretend to be asleep until your child has settled. Throughout this period do not attend to your baby directly unless he is in ill or in danger. If the baby is in danger (for example during an earthquake, or when he has a leg in the bars of the cot) respond to this appropriately by decreasing hazards and ensuring safety. If your child is ill or there is a significant

earthquake you will need to halt the programme and resume when your child is well again or things are settled. Remain sleeping in your baby's room for seven nights then return to your own room. Usually the baby accepts this change readily. Occasionally the baby will resume crying when you return to your room. In this case return to the baby's room for a night or two, this usually corrects the problem. When you have returned to your room, carry on the programme for a further three weeks. Throughout the program, treat all crying prior to 6am as a night waking and all crying after 6am as up for the day. Once your baby is up for the day increase light, sound and activity to enable your child to discriminate night and day.

In addition to these instructions, a dreamfeed was scheduled for approximately 10pm at night, owing to the infant's age and his Mother's preferences. The instructions for the dreamfeed were for Oliver's mother to remove Oliver from his cot whilst still asleep, feed him and then immediately place back into his cot. During this time there was to be no other interaction. It was also recommended the room be kept quiet and dark whilst feeding.

For the first seven days of the intervention the researcher called the infant's mother every day to check in. As the intervention went on the phone calls faded out, initially they became every second day, then every third, then twice a week and then once a week. During the maintenance period, Oliver experienced multiple bouts of illness including one-night's hospitalisation. Most illnesses were short in duration and included stomach bugs and colds. The one night hospitalisation was due to bronchiolitis. During this time the intervention was suspended and only resumed when his mother thought he was well enough and she felt comfortable to continue the intervention.

Oliver's mother continued to complete sleep diaries for 7 weeks from the beginning of the sleep intervention. Videosomnography data was also collected during this phase, 3 nights were collected 41 days after the intervention begun.

As mentioned during the intervention phase Oliver had multiple bouts of illness which impacted upon the behavioural intervention because his parents needed to respond to him more intensely. During the intervention period, Oliver and his family also had a holiday which was a potential disruption to Oliver's normal sleep and the intervention.

Follow up 2. Follow up data was collected 89 days after the behavioural intervention begun. The collection of this data was delayed by bouts of sickness which required the intervention to paused and resumed. The researcher waited until a time of relative stability before collecting this data to avoid effects of illness. During this phase a week of sleep diaries and 3 nights of videosomnography was collected. This data was used in the analysis of sleep state organisation.

Reliability between Sleep Diaries and VSG data.

Table 6: *Reliability between parent report sleep diaries and VSG data.*

	Kelly	Matt	Beth	Char	Oliver
Sleep onset delay	75%	83%	83%	100%	100%
Number of night wakings	100%	100%	100%	100%	83%

The reliability of the parent report diaries ranged between 75 and 100% when compared to the VSG data, indicating good reliability of the parent reported data.

Reliability of VSG Data

The two coders agreed between 86 to 100% of the time, also indicating good reliability of the coding.

Effect of Doll and Behavioural Intervention on Sleep as measured by Parent Reported

Sleep Diaries

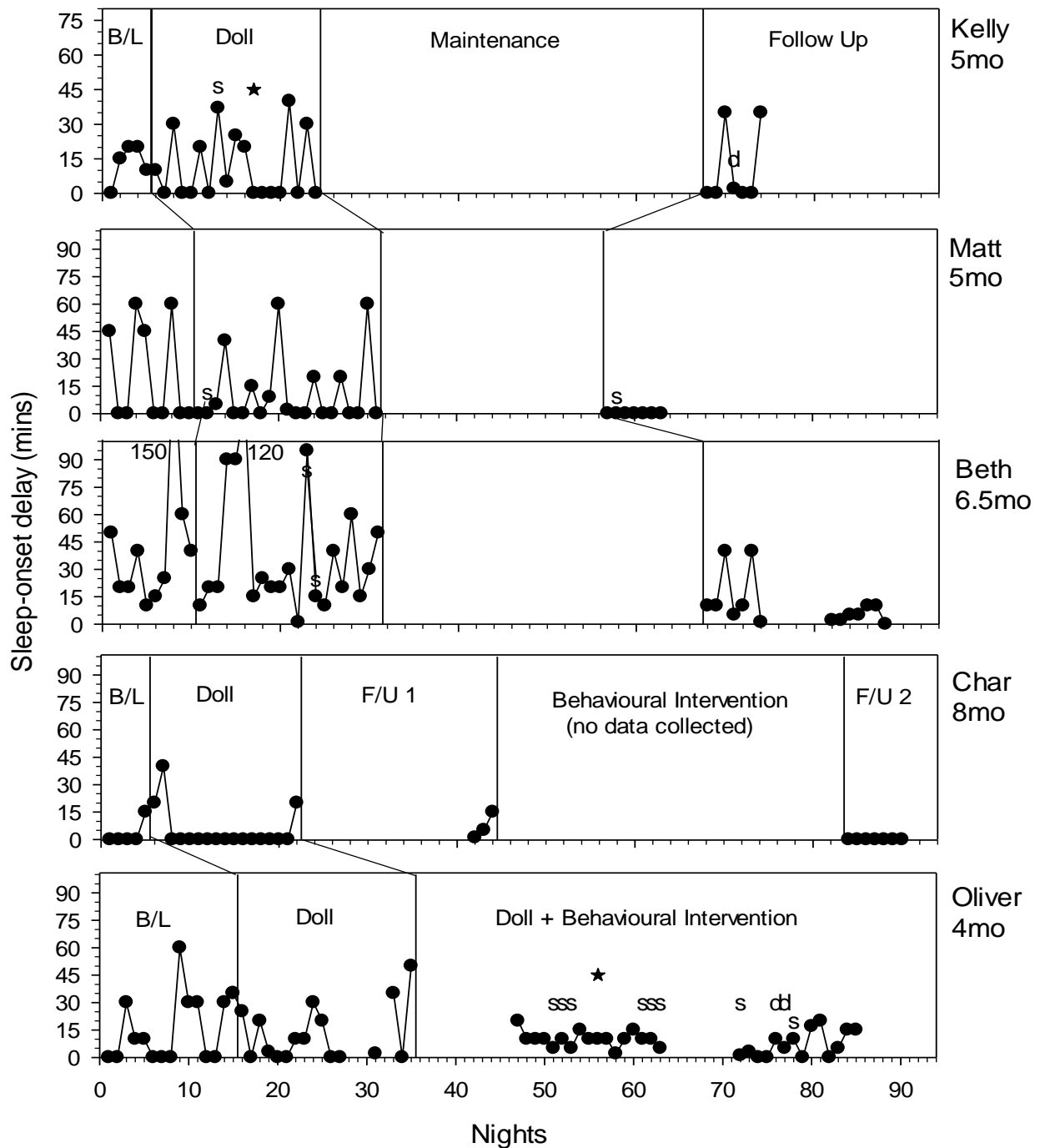
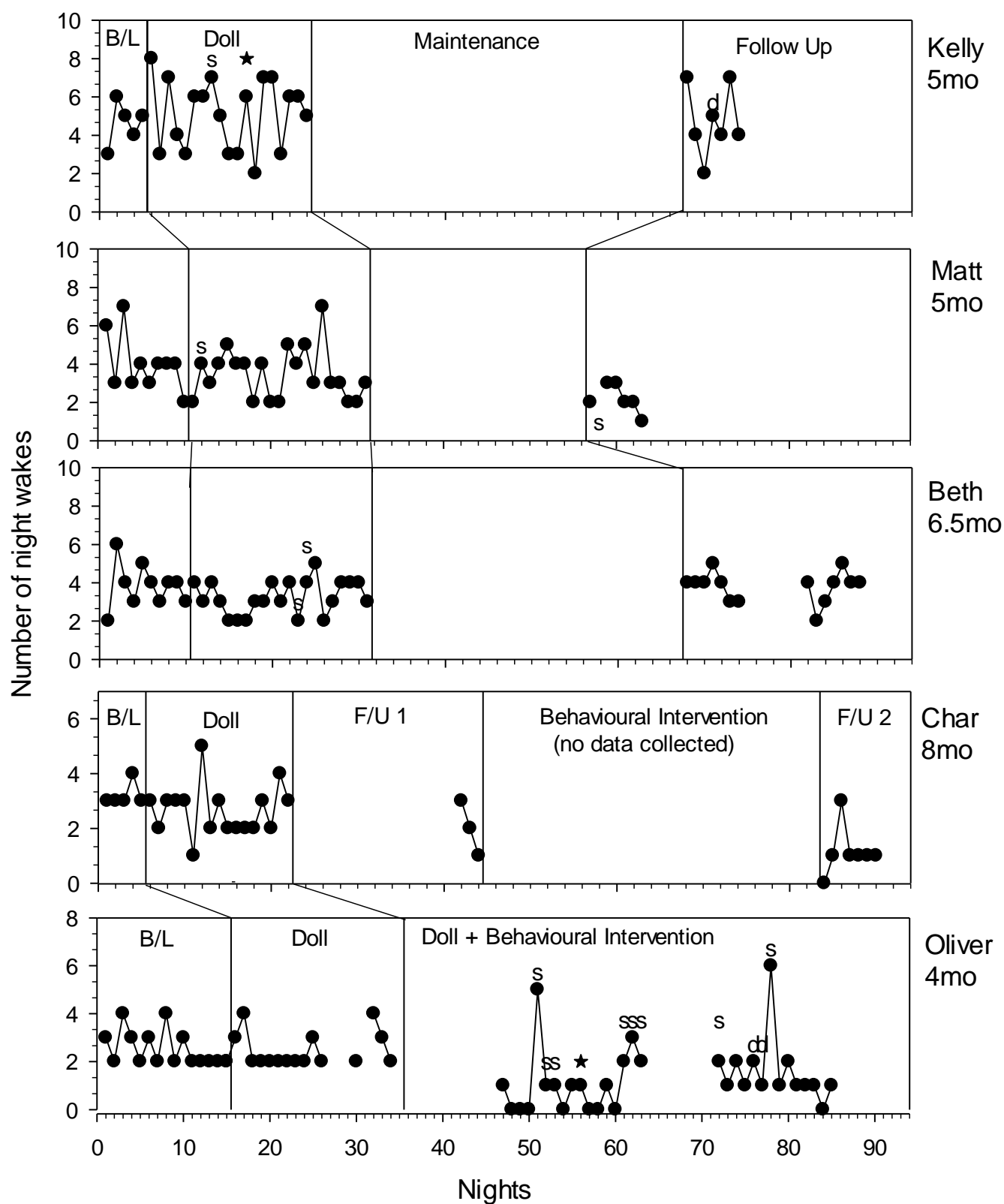


Figure 1: Sleep onset delay as measured by parent report sleep diaries across all phases



Key:

B/L: baseline, F/U: follow up, d: disturbance, s: sick, *: daylight savings

Figure 2: Number of night wakes as measured by parent reported diaries across all phases

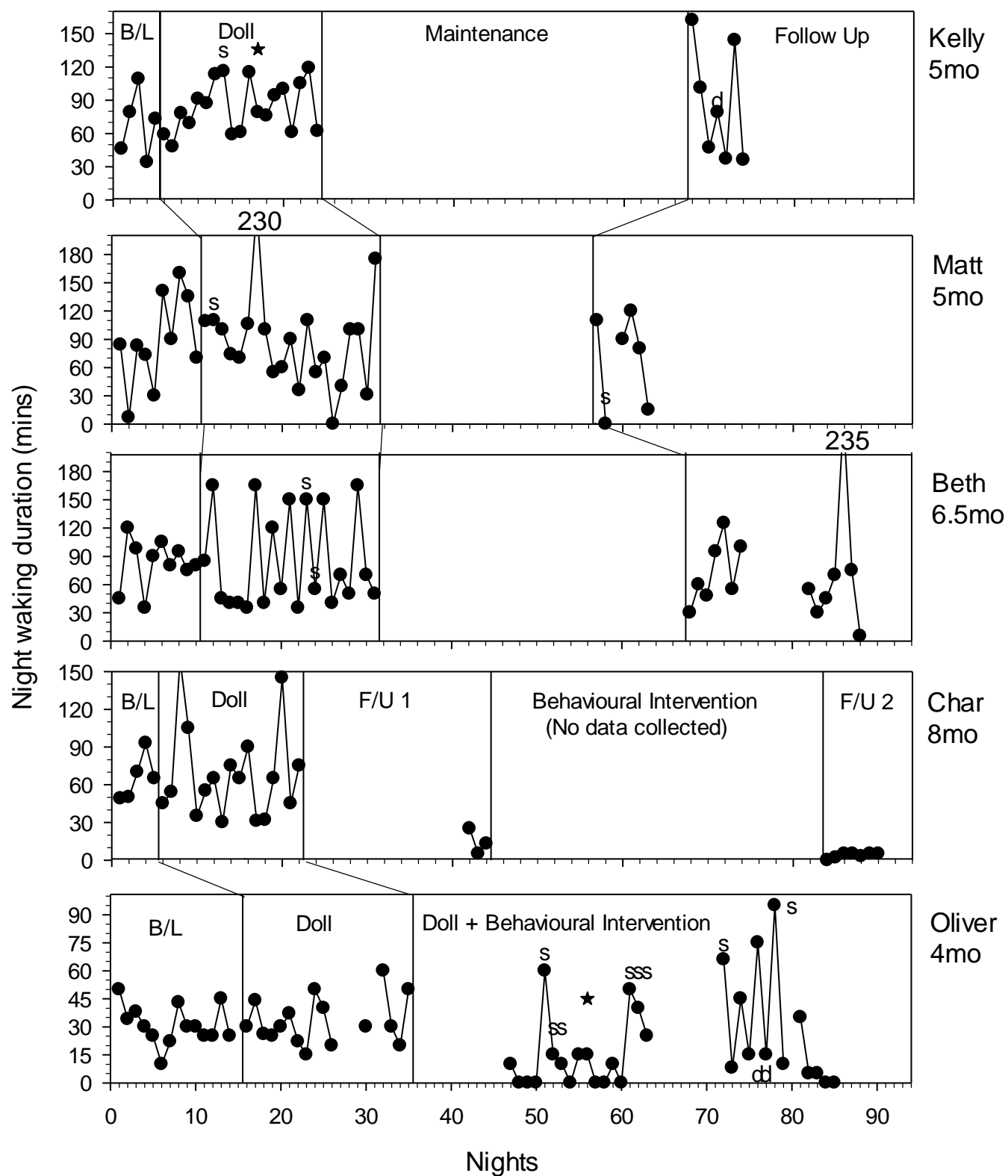


Figure 3: Night waking duration as measured by parent report diaries across all phases

Doll and parent report diaries. This section describes the effect of the doll intervention on sleep as observed by parent reported sleep diaries. This section discusses all phases of the studies for Kelly, Matt and Beth (baseline, intervention and follow up) and the first two phases for Char and Oliver (baseline and doll intervention).

Sleep onset delay. The length of each participant's sleep onset delay as recorded by their parents can be seen in Figure 1. In baseline, Kelly's sleep onset delay varied between 0 and 20 minutes, however for most nights it took Kelly between 15 – 20 minutes to fall asleep. Kelly's sleep onset delay showed little change in the intervention and follow up phase other than a slight increase in variability. A possible increase can be observed in the number of nights in which Kelly had no sleep onset delay, however there are also several nights in both intervention and follow up that Kelly's sleep onset delay increased when compared with baseline.

Matt's sleep onset delay in baseline varied between 0 and 60 minutes. On the nights with no sleep onset delay Matt mostly fell asleep feeding, and on the nights of sleep onset delay he was put to bed awake. Whilst no change was observed between baseline and doll intervention phases, a significant decrease in sleep onset delay was observed during follow up when compared with both baseline and intervention phases.

Beth's sleep onset delay varied from between 5 and 150 minutes in baseline. No change in Beth's sleep onset was observed between baseline and intervention, however Beth's sleep onset delay is seen to reduce markedly during the second follow up recordings.

Char showed very little variance of sleep onset delay in the baseline phase and does not show any difficulty with settling to sleep in any phase of the study.

Oliver's sleep onset delay varied from between 0 (feeding to sleep) and 60 minutes during baseline. No change in Oliver's sleep onset delay was observed between baseline and

the doll intervention phase. Oliver did not have a follow up phase as he immediately began a behavioural intervention following the conclusion of the doll intervention phase.

Number of night wakes. Figure 2 shows the number of night wakes per night for all participants throughout the course of the study.

In baseline, Kelly woke between 3 and 6 times a night. This remained steady throughout the intervention and follow up phases where Kelly continued to wake 3 times or more per night, with the very occasional night of only 2 wakes. In both the intervention and follow up phases, Kelly continued to have some nights where she woke between 4 and 7 times a night.

The number of times Matt woke each night did not change between the baseline and intervention phases. In both phases Matt woke between 2 and 7 times a night. Matt's night waking in follow up showed a slight decrease.

Beth's night waking is stable across all phases including baseline, intervention and follow up. Beth typically woke between 2 and 5 times a night in each phase.

When compared with baseline, Char's waking is seen to decrease slightly in the second half of the intervention phase, however this was not maintained as number of wakes began to increase again towards the end of the intervention phase. There was a slight decrease in Char's number of night wakes in follow up however.

During baseline, Oliver typically woke between 2 and 4 times a night, and this remained stable during the doll intervention period.

Duration of night waking. In Figure 3, the durations of each wake have been combined to represent the total duration of waking for each night, for each participant

throughout the study. As the data was collected via parent reported sleep diaries, this measure only reflects wakes which attracted parental attention such as by crying out.

No change was observed in the duration of Kelly's night waking between baseline and the intervention phase. There was also no change in follow up, instead there was an increase in variability of duration of waking during this phase, which included the longest awakenings since the beginning of the study.

Matt's duration of wake during the night also did not change between phases with Matt most often waking for 30 minutes or more per night throughout all phases.

In baseline, on 8 out of 10 nights Beth was awake from between 75 minutes and 120 minutes. In contrast to baseline, where Beth's duration of night wake followed a mostly stable pattern, Beth's duration of night waking became increasingly varied after the introduction of the doll. Her waking fluctuated between 30 to 60 minutes to 120 to 165 minutes a night.

Despite no apparent reduction in the duration of night waking between baseline and intervention for Char, a marked reduction was observed during the follow up phase. In both baseline and intervention Char was typically awake for between 30 and 90 minutes per night. In follow up Char's waking had reduced to between 30 minutes or less.

Oliver's duration of night waking showed no change between baseline and the Lulla Doll intervention. No comparison between baseline, intervention and follow up can be made for Oliver because he started a behavioural sleep intervention.

Behavioural intervention and parent report diaries. This sections describes the effect of the behavioural intervention as measured by parent reported sleep diaries for the two

participants who chose to undertake a behavioural intervention, Char and Oliver. It covers phase Follow Up 2 for Char and Behavioural Intervention for Oliver.

Sleep onset delay. As seen in Figure 1, Oliver's sleep onset delay is seen to decrease between baseline and behavioural intervention from between 0 and 60 minutes to an approximate 15 minutes or less. No effect of the behavioural intervention was observed for Char, who already had a short sleep onset at the beginning of the study.

Number of night wakes. The effect of the behavioural sleep intervention on parent reported night wakings can be seen in Figure 2. Char's night waking decreased following the behavioural sleep intervention, with Char only waking once or less on 6 out of 7 nights. Charlotte was also observed to sleep through the night for the first time in the study following the sleep intervention. Oliver's waking during the maintenance phase, following the parental presence procedure, was significantly varied, particularly when compared with baseline and doll intervention. However on the majority of nights during the behavioural intervention Oliver's waking did decrease to one waking a night or less.








Night waking duration. As seen in Figure 3, following the behavioural sleep intervention Char's duration of night waking is seen to decrease to 5 minutes or less. This change is maintained for the duration of the second follow up phase.

When compared with baseline, Oliver's duration of wake is seen to increase in variability after the behavioural sleep intervention. On some nights Oliver's duration of waking is seen to be significantly higher than in baseline and intervention. On other nights however duration of waking has seen to decrease when compared with baseline.

Videosomnography Measures of Sleep States

The second part of this chapter describes the effect of both the doll and behavioural intervention on aspects of sleep which were assessed using VSG. Averages from both intervention phases, doll and behavioural, were compared with an average baseline and graphed onto the same plot below. They are differentiated by filled shapes and unfilled shapes. The filled shapes, one for each participant, represent comparisons of baseline averages (axis x) and doll intervention averages (axis y), showing any effect of the doll intervention on the variables derived from the VSG data. The unfilled shapes, are comparisons of baseline averages (axis x) and post sleep intervention averages (axis y), showing any effect of behavioural intervention on the variables derived from the VSG data.

Table 6: Key for identification of participants in modified Brinley plots

Symbol	Description	Participant
	Filled circle	Kelly
	Filled diamond	Matt
	Filled triangle	Beth
	Filled inverted triangle	Char (Lulla doll)
	Filled square	Oliver (Lulla doll)
	Unfilled inverted triangle	Char (Behavioural intervention)
	Unfilled square	Oliver (Behavioural intervention)

Effect of Doll and Behavioural Intervention on Sleep State Variables as measured by Videosomnography

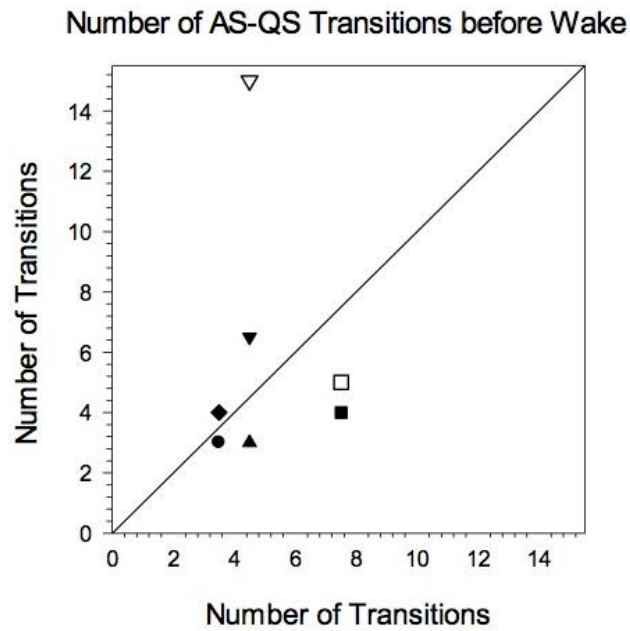


Figure 4: Number of sleep state transitions from VSG data.

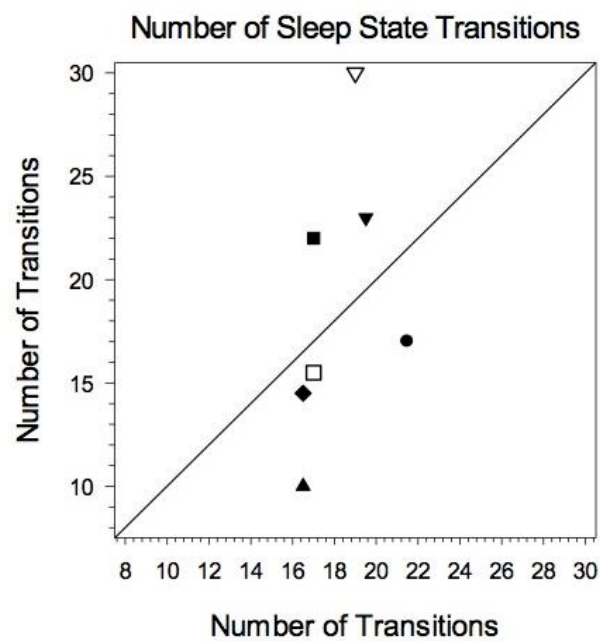


Figure 5: Number of AS-QS transition from VSG data

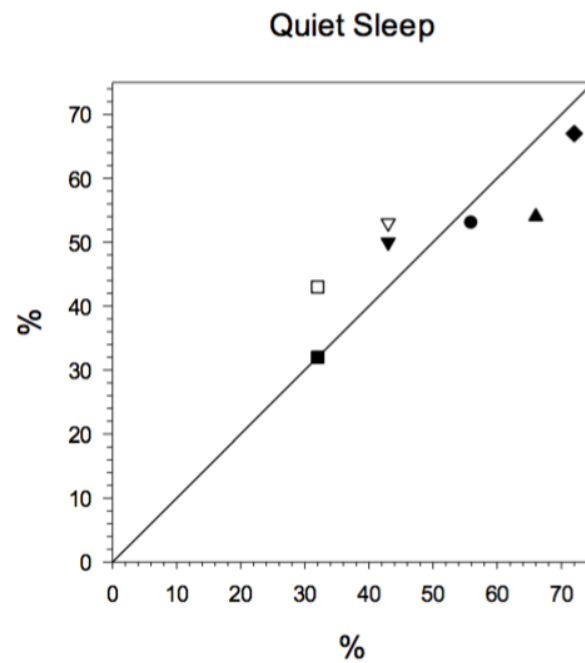


Figure 6: Percentage of sleep time spent in quiet sleep from VSG data

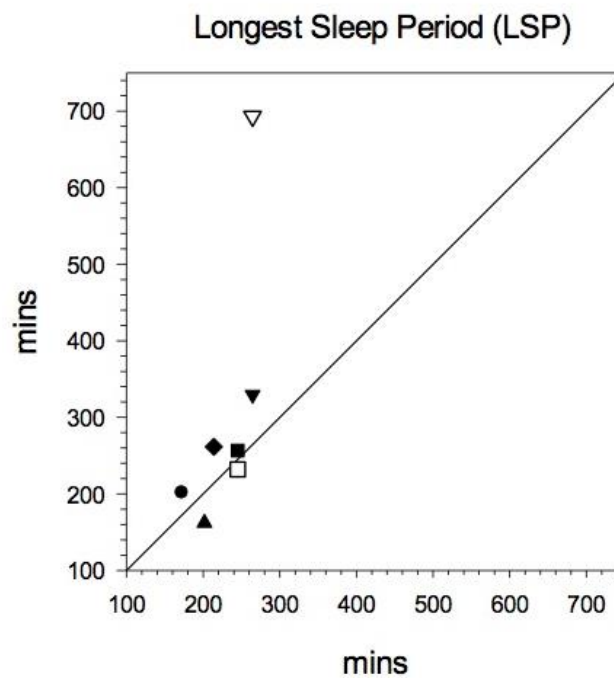


Figure 7: Longest sleep period from VSG data

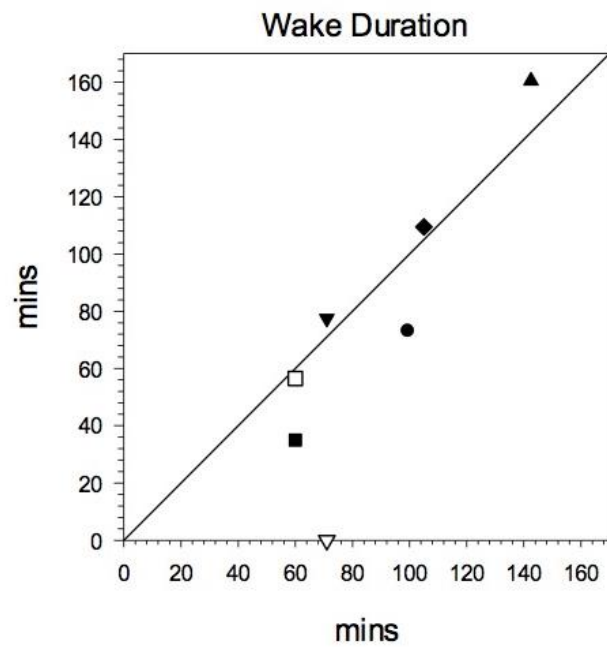


Figure 8: Wake duration from VSG data

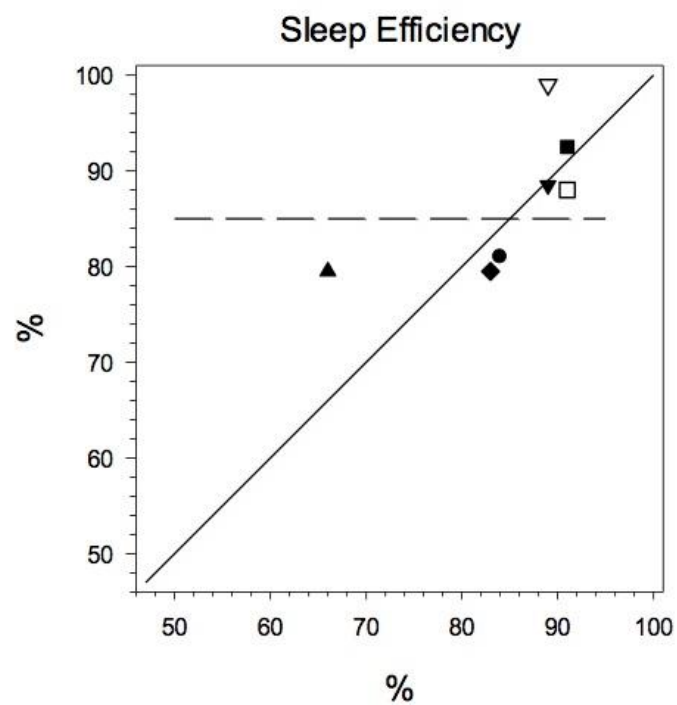


Figure 9: Sleep efficiency from VSG data

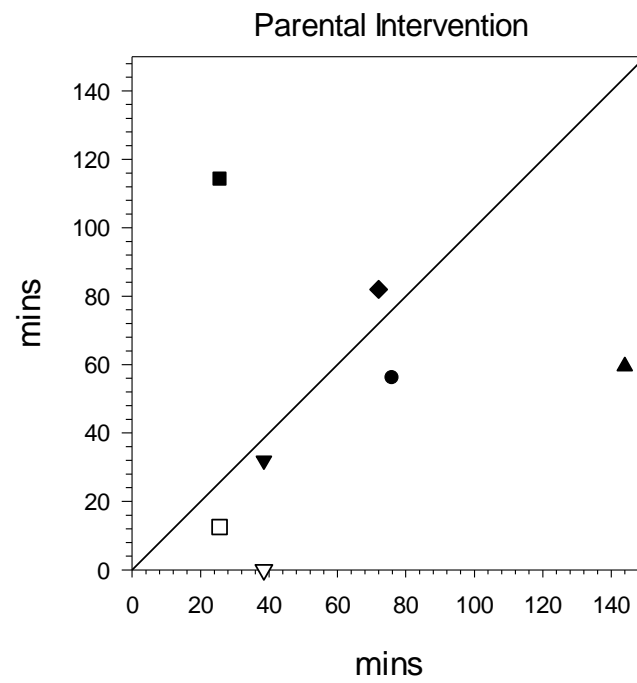


Figure 10: Duration of Parental Intervention from VSG data.

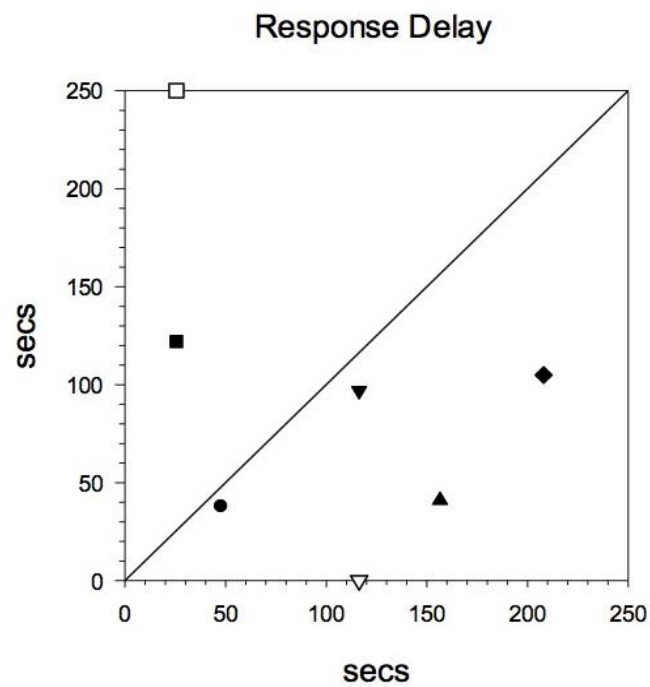


Figure 11: Delay of parental response following a signal from infant from VSG data

Doll intervention and VSG data. This section describes any changes that may have occurred in sleep state variables between baseline and doll intervention phase for all five participants.

Largest number of AS-QS transitions before wake. Figure 4 depicts the largest number of transitions between active sleep (AS) and quiet sleep (QS) an infant was able to achieve before a wake. Because many participants woke several times a night, the number of transitions made before a wake varied throughout the night. Therefore, the highest number of transitions was identified for each night.

No consistent trend is evident across the five participants when baseline scores are compared with doll intervention scores. Two out of five participants showed very little change in the number of transitions from AS to QS before wake, one participant showed an increase and the remaining two participants showed a decrease.

Number of sleep state transitions before wake. Figure 5 depicts how many sleep state transitions are observed to occur over the course of the night, including transitions from quiet sleep to active sleep as well as transitions from active sleep to quiet sleep.

As seen in Figure 4, two out of five participants had an increase in the number of sleep state transitions after the introduction to the doll when compared to baseline. Char went from an average of 19.5 transitions to 23 transitions and Oliver went from an average of 17 transitions to 22 transitions. One participant showed a small decrease from 16.5 transitions to 14.5 transitions with the two remaining participants showing a more marked decrease in the number of sleep state transitions throughout the night. Beth showed the largest decrease from an average of 16.5 transitions to an average of 10 transitions and Kelly showed a decrease from an average of 21.5 transitions to 17 transitions.

Quiet sleep. Figure 6 shows any changes in the percent of sleep time spent in quiet sleep between baseline and intervention phase for all participants. There was no consistent trend across participants when baseline averages were compared with doll intervention averages. Two out of five participants showed no change in the average portion of sleep time they spent in quiet sleep. One showed a small increase and the other two both showed a small decrease.

Longest sleep period. Comparisons of each participants longest sleep period (LSP) from baseline to doll intervention phase can be seen in Figure 7. For three out of five participants there was a small increase in the duration of the averages for longest sleep period between phases. For the other two participants, one showed no change between phases and the other showed a small decrease in their average LSP. Char showed the largest increase in duration with an average LSP of 264.5 minutes in baseline and an average LSP of 329.5 in the doll intervention phase, a difference of 65 minutes. Matt's average LSP increased by 47.5 minutes from an average LSP of 214 minutes in baseline to an average LSP of 261.50 minutes in doll intervention. Kelly had an increase from an average LSP of 172.5 minutes in baseline to an average LSP of 201 minutes in the doll intervention phase, a difference of 28.5 minutes. Oliver showed no change in the average length of his LSP and Beth showed a decrease in average length of her LSP by 39.5 minutes between baseline and doll intervention phase.

Wake duration. For all participants, the duration of time spent awake over the night time period can be seen in Figure 8. For this variable no consistent effect of the introduction of doll was observed. Two out five participants showed no change, two showed a decrease in the average time they spent awake over the night time period and the remaining participant

showed a moderate increase. Oliver's average decreased by 25 minutes and Kelly's averaged decreased by 26.5 minutes.

Sleep efficiency. As can be seen in Figure 9, there was no change in sleep efficiency between the baseline phase and doll phase for two out of five participants. Two showed a small decrease and one showed an increase. Of these four participants who showed little to no change, two participants remained below 85% efficiency and two remained above. Beth, the only participant to show any increase, showed an increase in sleep efficiency from baseline to doll intervention phase however still remained below 85% sleep efficiency.

Parental intervention. As seen in Figure 10, three out of five participants showed a decrease in the average time infants spent either in interaction with their parents or out of cot between baseline and doll intervention. Kelly and Char both showed a very small decrease while Beth showed a significant decrease, almost having her average. In contrast to these three participants, Matt and Oliver both showed an increase in time spent out of cot and duration of parental intervention. While Matt's increase was not marked, Oliver showed a large increase in the combination of time spend out of cot and time interacting with parents. In conclusion, there was no consistent effect of the Lulla Doll on time spent either out of cot or interacting with parents.

Response delay. As seen in Figure 11, for two out of five participants, the average time between a signal and their parents responding decreased markedly between baseline and doll intervention phase. In other words, parents began to respond more promptly to their infants cries after they started using the doll when compared with their responding previous to the introduction of the doll. Of the other participants, the time between a signal and parental response increased for one participant and for the remaining two participants there

was a very small decrease. In summary, there was no consistent effect of the doll on the time between an infant signalling and parent responding across all participants.

Behavioural intervention and VSG data. This section describes any changes in sleep state organisation for the participants, Char and Oliver, who undertook a behavioural intervention. It compares baseline averages with the averages from the final follow up phase for both participants.

Largest number of AS-QS transitions before wake. As seen in Figure 4, for Oliver, a small decrease in the average number of AS-QS transitions achieved before a wake from baseline to follow up was observed. For Charlotte, an marked increase in the average number of active to quiet sleep transitions before wake was observed between baseline and post sleep intervention.

Number of sleep state transitions before wake. As seen in Figure 5, when averages were compared between baseline and post sleep intervention, Char showed a larger increase in the average number of sleep state transitions. In contrast, Oliver showed a small decrease in the average number of sleep state transitions between phases.

Quiet sleep. In Figure 6, the average portion of sleep time spent in quiet sleep is compared for both participants between baseline and post sleep intervention. Both participants demonstrate a small increase in the average amount of sleep time spent in quiet sleep. Char showed increase from an average 43% to 53% and Oliver showed an increase from an average of 32% to an average of 43%.

Longest sleep period. In Figure 7, Char shows a significant increase in her average LSP between baseline and after the behavioural sleep intervention, with an increase in averages of 428.5 minutes. Oliver however showed a small decrease in his average LSP between phases of 13 minutes.

Wake duration. As seen in Figure 8, Oliver's average of time spent awake during the night-time did not change markedly, with only a very small decrease of 4.5 minutes observed between his baseline average of 60 minutes and his post sleep intervention average of 56.5 minutes. In contrast, Char's average decreased much more markedly from an average of 71 minutes awake in baseline phase to an average of 0 minutes awake in the post behavioural intervention phase.

Sleep efficiency. Figure 9 depicts any changes in sleep efficiency between baseline and sleep intervention. Oliver's score did not change markedly between phases, with only a very small decrease in sleep efficiency. In contrast, Char showed a large increase in sleep efficiency. Char's sleep efficiency average post behavioural sleep intervention moved to close to 100% from approximately 90% in baseline.

Parental intervention. As seen in Figure 10 following the behavioural sleep intervention, both participants show a decrease in time spent out of cot or interacting with parents. Char showed the most pronounced decrease with her post behavioural intervention average of 0 minutes. Oliver's decrease was less marked with a reduction of only 7.5 minutes after the behavioural intervention.

Parental response delay. There was a marked change for both participants between baseline and post behavioural intervention, as seen in Figure 11. The time it typically took for Char's parents to respond post intervention is seen to decrease on the graph in figure 10. This is because Char's parents no longer responded to any signals from Char that she was awake. For Oliver, the time it typically took his parents to respond after a signal is seen to increase significantly.

Parent Report of Doll Effectiveness

At the end of the study parents were asked if they saw any changes in their infants sleep from using the doll. Three parents reported a change in their infants' sleep, one reported a decrease in night wakings, one reported wakings were now more regular and another parent also noted her infant slept for longer. One parent reported it had helped decrease settling time at night. It was also reported by one parent that her infant was less distressed upon waking and the intensity of cry had decreased. Two parents also reported that their infant had displayed preference for the doll and liked to interact with it. One parent reported a time when their infant was upset by the doll and as a result the parents removed it from the cot temporarily.

One parent reported that she liked the fact the doll provided some comfort and familiarity for her child when she was not able to be in her room with her.

Of the 4 parents who loaned dolls, two parents purchased the doll at the end of the study to continue on with using the doll, the other two decided to not continue with the doll. The parent who had purchased the doll as their own also decided to continue on with use.

Chapter Four

Discussion

The purpose of this research study was to ascertain the effectiveness of a heart beating, breathing doll on improving infant sleep, as measured by parental perception and by objective videosomnography.

The following two research questions were posed:

1. Does a heart beating breathing doll have any effect on aspects of infant sleep as experienced by the infant's parents?
2. Does a heart beating breathing doll show any effect on sleep state organisation?

Research Questions Answered

Research Question One. Results of this study suggest that the doll did not consistently improve infant sleep when measured by parent report diary. While some parents reported an improvement in certain aspects of sleep, these improvements were not replicated in other participants. There was no change in sleep onset delay for three out of five participants, a slight decrease in number of night wakings for only two participants and a reduction in duration of night waking for only one participant.

Even for the two participants who did show a reduction in sleep onset delay, this was observed during the follow up phase. In Matt's case, he was fed to sleep on all nights of follow up, resulting in the appearance of a reduction in sleep onset delay. In Beth's case the delay in effect may indicate the need for long exposure to the doll, sleep maturation or other changes in her life. In conclusion, the lack of replication of a decrease in sleep onset delay across the other three participants and no clear changes in the other parent reported measures indicates there is no causal relationship between the doll and parent-reported sleep.

Research Question Two. The second research question of this study was to ascertain if the doll had any effect on sleep state organisation, namely, a decrease in time spent awake, an increase in sleep efficiency, an increase in the longest sleep period, an increase in the number of AS-QS transitions before a wake and a decrease in the number of sleep state transitions. Much like the parent reported measures, some infants showed small improvements on certain aspects of sleep state organisation, however the improvement was not consistent across all participants and variables. For all variables, except for LSP, no more than two participants saw an improvement for each variable, demonstrating little replication. While three participants demonstrated an increase in LSP, the increase observed was small in nature. Replication of an effect across participants is vital for studies utilising a within participants' design as replication is necessary for a casual relationship to be drawn between the intervention and change.

Effect on Parenting Practices

Results of the study showed that the introduction of the doll also did not have a consistent effect on parenting practices across the group. The time it typically took parents to respond to their signalling infant increased after the introduction of the doll for two participants, decreased for one and remained unchanged for the remaining two. The time parents spent either interacting with their infants in their cots also did not change consistently across the group. In their study, Novosad and Thoman (2003) found that post the introduction of the breathing bear companion, participants' mothers rated their infants more favourably despite no change in duration of crying. In this study there was the possibility that due to an increase of reassurance from the doll parents could increase the delay of their response or decrease their interaction time with their infants. However this was not the case.

Why Was The Doll Not Effective?

Age related differences between the infants in the current study and the studies described previously, such as studies of Kangaroo Care, white noise and the Breathing Bear may explain the discrepancy in results. Infants in the research areas just described were predominantly either premature infants or infants aged under 1 week. This is in contrast to the infants in this study who were aged between 4 and 8 months. Given that infant sleep undergoes significant transformation within the first 4 months of life (Anders & Keener, 1985; Goodlin-Jones et al., 2001) it is therefore possible that the differences in results between the current study and previous studies described are age related. Furthermore, the premise of kangaroo care research is that providing continuation of conditions which were constant whilst the infant was in utero, such as heartbeat and sound, is protective for infants. Therefore, it is possible that the delay between gestation and introduction of the doll is too long for these conditions to still provide benefit for the infants in this current study.

There are also deviations in settings between previous research and the current study which may explain the discrepancy in results. Much of the previous research was conducted in hospital settings or elsewhere to the home setting. It has previously been suggested that white noise may provide a 'screen' for other disruptive noises (Tulloch et al., 1964) so it is possible this mechanism was not as crucial in the home setting.

Whilst the results of this study are in contrast to the previous studies of white noise, kangaroo care and the breathing bear, they can be considered consistent with the transactional model of sleep developed by Sadeh and Anders (1993) and adapted by Sadeh et al. (2010). The transactional model acknowledges the role of the environment on sleep, including factors such as physical conditions, however it places caregiving behaviour as the most immediate and direct factor that contributes to shaping infant sleep. In particular, interactions around

night time and sleep onset are described as those most closely related to infant sleep problems (Sadeh et al., 2010). Therefore, the lack of significant change in infant sleep in this study, is not inconsistent with the transactional model given that there was no change in parental caregiving behaviours at night. The model would indicate that changing environmental conditions alone without changing parental behaviour is not sufficient to significantly alter infant sleep.

Parent Report of Doll Effectiveness

While the other measures in this study did not detect a marked effect of the doll on infant sleep some parents did report an improvement, such as a decrease in night wakings, more regularity with wakings and another parent also noted her infant slept for longer before a wake. Other changes included a decrease in intensity of cry. It is possible that the other measures in this study did not capture the elements of change that parents were able to, such as timing/organisation of wakings through the night and intensity of cry.

Behavioural Intervention and Sleep

The choice of two families to undertake a behavioural intervention following the doll intervention allowed for the opportunity to also examine the effect of the behavioural intervention on infant sleep.

Behavioural intervention and parent report sleep diaries. Using parent report diaries several changes in the infants' sleep were observed. For Oliver, a marked decrease in his sleep onset delay was observed after the behavioural intervention. In addition, his ability to initiate sleep independently at bedtime developed significantly from prior to the intervention. Oliver's night waking showed a less clear response to the intervention, however he experienced multiple bouts of illness, and a family holiday during this time which were likely to effect the intervention. Despite this, on the majority of nights in the maintenance

period, Oliver's waking did decrease to one wake per night which is an improvement from both baseline and the doll intervention period. There are also several nights in which wakings were eliminated completely and Oliver was seen to 'sleep through'. Like his number of night wakes, Oliver's duration of night waking varied significantly, particularly on nights of illness and between illnesses.

There was no change in Char's, already low, sleep onset delay. However, Char's night waking decreased after the sleep intervention from baseline and doll intervention. While Char continued to wake following the intervention and signal during these wakes she signalled for much shorter of time and was able to reinitiate sleep independently. Prior to the behavioural intervention Char would continue to signal until she received parental assistance to return to sleep. The duration of night waking observed for Char was also observed to significantly decrease post sleep intervention.

Behavioural intervention and sleep state organisation change. The effect of the behavioural intervention on sleep state organisation varied between participants. For Char, many changes in sleep-state organisation occurred which suggested the behavioural sleep intervention was effective at encouraging increased organisation of sleep states. These included, an increase in the largest number of AS-QS transitions before a wake, an increase in her LSP, a decrease in wake duration and an increase in sleep efficiency. These variables suggest Char's sleep has been improved by more time spent asleep during time in bed, less time spent awake, longer periods of sustained sleep and an increased tolerance for AS-QS transitions before waking. These are changes are all consistent with a more mature sleep pattern. Only one variable did not show a change in the direction expected. Char did not show a decrease in the total number of sleep state transitions throughout the night.

In contrast to Char, Oliver's sleep state organisation was not observed to consistently improve. Had Oliver's sleep state organisation improved as a result of the behavioural intervention, it would be expected that Oliver's LSP increased, however a decrease was observed. No change was observed for Oliver's wake duration and sleep efficiency, which were expected to decrease and increase respectively. There was a small decrease in the total number of sleep state transitions for Oliver, which was a favourable result, however there was also a decrease in the number of AS-QS transitions before wake.

Was the behavioural intervention effective?

The results from the parent sleep diaries suggest the behavioural intervention was successful for reducing the number of night wakings and duration of night wakings for Char and reducing sleep onset delay for Oliver. Oliver's night wakings and duration of night waking was also observed to decrease on the nights on which he was not unwell or had a disturbance to his sleep, even though there was significant variance observed around the nights of illness.

These results are consistent with previous research documenting the relationship between infant sleep and parental behaviour. During the intervention for both participants, parental presence at bedtime and after wakings, as well as other caregiving behaviours were removed, with the intention of encouraging the ability for the infants' capacity to self-soothe. Many studies document that parental interactions around bedtime and after night wakings can inhibit infants' ability to self-soothe and result in infants continuing to signal for parental assistance to reinitiate sleep after an awakening (Adair et al., 1991; Morrell & Cortina-Borja, 2002; St James-Roberts et al., 2017). The reduction in sleep onset delay for Oliver, as well as his ability to fall asleep independently as well as the decrease in signalled night wakings for

Char suggest the behavioural intervention was successful in encouraging both infants to develop their abilities to self-soothe and reinitiate sleep independently.

The variance in night waking and duration of night waking which was observed for Oliver is also consistent with previous research of extinction based procedures. On the nights of illness for Oliver it was necessary and appropriate for his parents to return to engaging in more intensive caregiving behaviours, such as responding to night wakings, providing physical comfort and feeding. Unfortunately, it is known that resuming parental attention for signalling is reinforcing for infants to resume and continue to signal (France & Blampied, 1999) and while it was unavoidable due to illness in Oliver's case, it was likely to increase the likelihood of Oliver to continue to signal upon waking.

The behavioural intervention was also observed to improve Char's sleep state organisation, as demonstrated by an increase in the largest number of AS-QS transitions before a wake, an increase in her LSP, a decrease in wake duration and an increase in sleep efficiency. The observation of these improvements for Char alone indicate that the increased organisation of her sleep states is likely to be the result of the environmental manipulation of the behaviour intervention as opposed to the result of biological maturation. If maturation alone was likely to be the cause of improved organisation similar results would have been observed for other infants in the study.

Limitations

Several limitations are evident for this research study. The first limitation of the study is that the doll may have demonstrated greater effects on the sleep if three infants had not had prior exposure to white noise. Inclusion criteria ensured that participants had not previously used a doll, however other common forms of white noise were not excluded.

Another limitation of the study was the difficulty to always ensure the camera equipment covered the entire area of the cot. At some points the camera did not capture the entire infants body and this may have affected the researchers' ability to code infant states at some points. In the future, it may be useful to use tripods and cameras with wider angles to ensure the cot is always full visible.

The abbreviated coding of the VSG data is also a limitation of this study. Due to the time intensive nature of the coding, only two nights in each phase were coded and used in the final data analysis. Coding more nights per each phase would allow further analysis methods to be employed. It would also provide a more representative picture of the infants' sleep at each stage of the study. A third limitation is also related to the time intensive nature of the VSG data. For practicality, only a small portion of the VSG data was able to be coded for reliability for the study. The lack of data collection during Char's behavioural intervention is also a limitation to this study.

Future Research

In order to fully elucidate the effectiveness of the doll on infant sleep it would be beneficial for further research to assess the effect of the doll with a wider participant group and it's use in another format. Given the hypothesis that age was a barrier to the effectiveness of the doll with the current participant group it would be particularly valuable to study the doll with younger infants. It may be particularly enlightening to assess the potential effects of the doll with infants who are exposed to the doll from birth.

In addition, it may be beneficial to assess the effectiveness of the doll when it is used in an alternative way to this study. During the recruitment process of this study it became apparent that many parents are interested in using the doll to support their infant to transition

from co-sleeping to sleeping independently. This is another avenue which may warrant future investigation to evaluate the potential of the doll.

Given the role parental practices played in improving infant sleep in this study it would also be important for future research to consider the effects of parental practices on shaping infant sleep.

Strengths of the Study

This study contributes to current field of literature by addressing many gaps. Currently there is little research investigating the use of white noise to improve infant sleep, particularly with infants in the first year of life. There is also very little research on white noise in the home environment. This study contributes to both these gaps in literature.

This study also contributes to the literature as it is the first study to empirically evaluate the heart beating breathing doll for improving infant sleep. There has been previous study of both the breathing aspect of the doll and heart beat aspect of the doll separately on improving infant sleep but this is the first study to investigate both the aspects together in the form of the Lulla Doll.

The dual use of parent sleep diaries and videosomnography data is also a strength of this study as it allowed many aspects of infant sleep to be monitored for change.

Conclusion

This current study aimed to ascertain the effectiveness of a heart beating breathing doll on infant sleep. The study did not find a consistent improvement in infant sleep across participants, as measured by sleep onset delay, number of night wakings or duration of night waking from the introduction of the doll. Furthermore, no consistent effect on the sleep state organisation of the infants was observed after use of the doll. Whilst this finding is in contrast

to some previously reported findings, it is possible that the discrepancy between populations studied in previous studies and the participants included in this study contributed to the lack of effect. The behavioural intervention was found to be effective in reducing the number of night wakings, and duration of night wakings for one participant as well as changing her VSM sleep states, and effective for improving sleep onset delay for the other participant. Future research may investigate use of the doll with differing populations, however considering the successful result of the behavioural intervention in this study it is also important to consider the role of parental behaviours in shaping infant sleep.

References

- Adair, R., Bauchner, H., Philipp, B., Levenson, S., & Zuckerman, B. (1991). Night waking during infancy: role of parental presence at bedtime. *Pediatrics*, 87(4), 500-504.
- Anders, T. F., Halpern, L. F., & Hua, J. (1992). Sleeping Through the Night: A Developmental Perspective. *Pediatrics*, 90(4), 554.
- Anders, T. F., & Keener, M. A. (1985). Developmental course of nighttime sleep-wake patterns in full-term and premature infants during the first year of life: I. *Sleep: Journal of Sleep Research & Sleep Medicine*, 8(3), 173-192.
- Anders, T. F., & Sostek, A. M. (1976). The use of time lapse video recording of sleep-wake behavior in human infants. *Psychophysiology*, 13(2), 155-158.
- Bernier, A., Carlson, S. M., Bordeleau, S., & Carrier, J. (2010). Relations between physiological and cognitive regulatory systems: infant sleep regulation and subsequent executive functioning. *Child Development*, 81(6), 1739-1752. doi:10.1111/j.1467-8624.2010.01507.x
- Brackbill, Y. (1970). Acoustic variation and arousal level in infants. *Psychophysiology*, 6(5), 517-526. doi:10.1111/j.1469-8986.1970.tb02241.x
- Brackbill, Y. (1975). Continuous stimulation and arousal level in infancy: effects of stimulus intensity and stress. *Child Development*, 46(2), 364-369. doi:10.1111/j.1467-8624.1975.tb03320.x
- Brackbill, Y., Adams, G., Crowell, D. H., & Gray, M. L. (1966). Arousal level in neonates and preschool children under continuous auditory stimulation. *Journal of Experimental Child Psychology*, 4(2), 178-188. doi:10.1016/0022-0965(66)90018-X
- Brescianini, S., Volzone, A., Fagnani, C., Patriarca, V., Grimaldi, V., Lanni, R., Stazi, M. A. (2011). Genetic and environmental factors shape infant sleep patterns: a study of 18-month-old twins. *Pediatrics*, 127(5), 1296-1302.
- Burnham, M. M., Goodlin-Jones, B. L., Gaylor, E. E., & Anders, T. F. (2002). Nighttime sleep-wake patterns and self-soothing from birth to one year of age: a longitudinal intervention study. *J Child Psychol Psychiatry*, 43(6), 713-725.
- Campbell-Yeo, M., Disher, T., Benoit, B., & Johnston, C. (2015). Understanding kangaroo care and its benefits to preterm infants. *Pediatric Health, Medicine and Therapeutics*, 2015, 15-32. doi:10.2147/PHMT.S51869
- Carskadon, M. A., & Dement, W. C. (2005). Normal human sleep: an overview. *Principles and practice of sleep medicine*, 4, 13-23.
- Cattaneo, A., Davanzo, R., Worku, B., Surjono, A., Echeverria, M., Bedri, A., Tamburlini, G. (1998). Kangaroo mother care for low birthweight infants: a randomized controlled

- trial in different settings. *Acta Paediatrica*, 87(9), 976-985. doi:10.1111/j.1651-2227.1998.tb01769.x
- Chapman, E. (2017). *Infant sleep disturbances: contrasting perspectives on intervention for Infant Sleep Disturbance (ISD) within popular media culture*. (Master's thesis, University of Canterbury, Christchurch, New Zealand). Retrieved from <http://hdl.handle.net/10092/13663>
- Charpak, N., Gabriel Ruiz, J., Zupan, J., Cattaneo, A., Figueroa, Z., Tessier, R., . . . Worku, B. (2005). Kangaroo Mother Care: 25 years after. *Acta Paediatrica*, 94(5), 514-522. doi:10.1111/j.1651-2227.2005.tb01930.x
- Charpak, N., & Ruiz, J. G. (2016). The Kangaroo Mother Care Method: From scientific evidence generated in Colombia to worldwide practice. *Journal of Clinical Epidemiology*.
- Charpak, N., Ruiz-Pelaez, J. G., Figueroa de C, Z., & Charpak, Y. (1997). Kangaroo Mother versus traditional care for newborn infants \leq 2000 grams: a randomized, controlled trial. *Pediatrics*, 100(4), 682-688. doi:10.1542/peds.100.4.682
- Cook, F., Giallo, R., Petrovic, Z., Coe, A., Seymour, M., Cann, W., & Hiscock, H. (2017). Depression and anger in fathers of unsettled infants: A community cohort study: Fathers of unsettled infants. *Journal of Paediatrics and Child Health*, 53(2), 131-135. doi:10.1111/jpc.13311
- Davis, K. F., Parker, K. P., & Montgomery, G. L. (2004). Sleep in infants and young children: Part one: normal sleep. *Journal of Pediatric Health Care*, 18(2), 65-71. doi:[http://dx.doi.org/10.1016/S0891-5245\(03\)00149-4](http://dx.doi.org/10.1016/S0891-5245(03)00149-4)
- DeLeon, C. W., & Karraker, K. H. (2007). Intrinsic and extrinsic factors associated with night waking in 9-month-old infants. *Infant Behavior and Development*, 30(4), 596-605.
- Detterman, D. K. (1978). The effect of heartbeat sound on neonatal crying. *Infant Behavior and Development*, 1, 36-48.
- Eckerberg, B. (2004). Treatment of sleep problems in families with young children: effects of treatment on family well-being. *Acta Paediatrica*, 93(1), 126-134. doi:10.1111/j.1651-2227.2004.tb00686.x
- Ednick, M., Cohen, A. P., McPhail, G. L., Beebe, D., Simakajornboon, N., & Amin, R. S. (2009). A review of the effects of sleep during the first year of life on cognitive, psychomotor, and temperament development. *Sleep*, 32(11), 1449-1458.
- Fagioli, I., Ficca, G., & Salzarulo, P. (2002). Awakening and sleep-wake cycle in infants. In P. Salzarulo & G. Ficca (Eds.), *Awakening and Sleep-Wake Cycle across Development* (pp. 94-114). Philadelphia, PA, USA: John Benjamins Publishing Company.

- Feldman, R. (2004). Mother-infant skin-to-skin contact (Kangaroo Care): theoretical, clinical, and empirical aspects. *Infants & Young Children: An Interdisciplinary Journal of Early Childhood Intervention*, 17(2), 145-161.
- Feldman, R., & Eidelman, A. I. (2003). Skin-to-skin contact (Kangaroo Care) accelerates autonomic and neurobehavioural maturation in preterm infants. *Developmental Medicine & Child Neurology*, 45(4), 274-281. doi:10.1017/S0012162203000525
- Feldman, R., Rosenthal, Z., & Eidelman, A. I. (2014). Maternal-preterm skin-to-skin contact enhances child physiologic organization and cognitive control across the first 10 years of life. *Biological psychiatry*, 75(1), 56. doi:10.1016/j.biopsych.2013.08.012
- Feldman, R., Weller, A., Sirota, L., & Eidelman, A. I. (2002). Skin-to-Skin Contact (Kangaroo Care) promotes self-regulation in premature infants: sleep-wake cyclicity, arousal modulation, and sustained exploration. *Developmental Psychology*, 38(2), 194-207. doi:10.1037/0012-1649.38.2.194
- Ferber, S. G., & Makhoul, I. R. (2004). The effect of skin-to-skin contact (Kangaroo Care) shortly afterbirth on the neurobehavioral responses of the term newborn: a randomized, controlled trial. *Pediatrics*, 113(4), 858-865. doi:10.1542/peds.113.4.858
- Fisher, A., van Jaarsveld, C. H., Llewellyn, C. H., & Wardle, J. (2012). Genetic and environmental influences on infant sleep. *Pediatrics*, peds. 2011-1571.
- Fisher, J., Rowe, H., Hiscock, H., Jordan, B., Bayer, J., Colahan, A., & Amery, V. (2011). *Understanding and responding to unsettled infant behaviour*. Retrieved from https://www.aracy.org.au/publications-resources/command/download_file/id/158/filename/Understanding_and_responding_to_unsettled_infant_behaviour.pdf
- Forquer, L. M., & Johnson, C. M. (2005). Continuous white noise to reduce resistance going to sleep and night wakings in toddlers. *Child & Family Behavior Therapy*, 27(2), 1-10. doi:10.1300/J019v27n02_01
- France, K. G., & Blampied, N. M. (1999). Infant sleep disturbance: Description of a problem behaviour process. *Sleep Medicine Reviews*, 3(4), 265-280. doi:http://dx.doi.org/10.1053/smr.1999.0071
- France, K. G., & Blampied, N. M. (2005). Modifications of systematic ignoring in the management of infant sleep disturbance: efficacy and infant distress. *Child & Family Behavior Therapy*, 27(1), 1-16. doi:10.1300/J019v27n01_01
- Galland, B. C., Taylor, B. J., Elder, D. E., & Herbison, P. (2012). Normal sleep patterns in infants and children: A systematic review of observational studies. *Sleep Medicine Reviews*, 16(3), 213-222. doi:10.1016/j.smr.2011.06.001
- Gertner, S., Greenbaum, C. W., Sadeh, A., Dolfin, Z., Sirota, L., & Ben-Nun, Y. (2002). Sleep-wake patterns in preterm infants and 6 month's home environment:

- implications for early cognitive development. *Early Human Development*, 68(2), 93-102.
- Goodlin-Jones, B. L., Burnham, M. M., Gaylor, E. E., & Anders, T. F. (2001). Night waking, sleep-wake organization, and self-soothing in the first year of life. *Journal of Developmental and Behavioral Pediatrics*, 22(4), 226-233. doi:10.1097/00004703-200108000-00003
- Guyer, C., Huber, R., Fontijn, J., Bucher, H. U., Nicolai, H., Werner, H., . . . Jenni, O. G. (2015). Very preterm infants show earlier emergence of 24-hour sleep-wake rhythms compared to term infants. *Early Human Development*, 91(1), 37-42.
- Halpern, L. F., Anders, T. F., Garcia Coll, C., & Hua, J. (1994). Infant temperament: Is there a relation to sleep-wake states and maternal nighttime behavior? *Infant Behavior and Development*, 17(3), 255-263. doi:10.1016/0163-6383(94)90004-3
- Henderson, J. M., France, K. G., Owens, J. L., & Blampied, N. M. (2010). Sleeping through the night: the consolidation of self-regulated sleep across the first year of life. *Pediatrics*, 126(5), e1081-e1087.
- Henderson, J. M. T., France, K. G., & Blampied, N. M. (2011). The consolidation of infants' nocturnal sleep across the first year of life. *Sleep Medicine Reviews*, 15(4), 211-220. doi:10.1016/j.smrv.2010.08.003
- Hiscock, H., & Fisher, J. (2015). Sleeping like a baby? Infant sleep: Impact on caregivers and current controversies. *Journal of Paediatrics and Child Health*, 51(4), 361-364. doi:10.1111/jpc.12752
- Hiscock, H., & Wake, M. (2001). Infant sleep problems and postnatal depression: A community-based study. *Pediatrics*, 107(6), 1317.
- Ingersoll, E. W., & Thoman, E. B. (1994). The breathing bear: Effects on respiration in premature infants. *Physiology & Behavior*, 56(5), 855-859. doi:10.1016/0031-9384(94)90315-8
- Jian, N., & Teti, D. M. (2016). Emotional availability at bedtime, infant temperament, and infant sleep development from one to six months. *Sleep Medicine*, 23, 49-58.
- Lenz, A. S. (2015). Using single-case research designs to demonstrate evidence for counseling practices. *Journal of Counseling & Development*, 93(4), 387-393. doi:10.1002/jcad.12036
- Ludington-Hoe, S. M., Johnson, M. W., Morgan, K., Lewis, T., Gutman, J., Wilson, P. D., & Scher, M. S. (2006). Neurophysiologic assessment of neonatal sleep organization: preliminary results of a randomized, controlled trial of skin contact with preterm infants. *Pediatrics*, 117(5), e909-e923.
- Lulladoll.com. (2016). Lulla Doll. Retrieved from <https://lulladoll.com/pages/about-us>

- Martin, J., Hiscock, H., Hardy, P., Davey, B., & Wake, M. (2007). Adverse associations of infant and child sleep problems and parent health: an Australian population study. *Pediatrics*, 119(5), 947-955.
- Mattern, J. (2017). Parents in a Mad Dash to Snag Doll That Lulls Babies to Sleep. *sheknows*.
- McGraw, K., Hoffmann, R., Harker, C., & Herman, J. H. (1999). The development of circadian rhythms in a human infant. *Sleep*, 22(3), 303-310.
- Mindell, J. A., Sadeh, A., Kwon, R., & Goh, D. Y. T. (2015). Relationship Between Child and Maternal Sleep: A Developmental and Cross-Cultural Comparison. *Journal of pediatric psychology*, 40(7), 689-696. doi:10.1093/jpepsy/jsv008
- Mitru, G., Millrood, D. L., & Mateika, J. H. (2002). The impact of sleep on learning and behavior in adolescents. *Teachers College Record*, 104(4), 704-726. doi:10.1111/1467-9620.00176
- Moore, T., & Ucko, L. E. (1957). Night waking in early infancy. I. *Archives of disease in childhood*, 32(164), 333.
- Morgan, D., & Morgan, R. (2009). Multiple Baseline Designs. In R. Morgan & D. Morgan (Eds.), *Single-Case research methods for the behavioral and health sciences* (pp. 125-160). Thousand Oaks, California. Retrieved from <http://methods.sagepub.com/book/single-case-research-methods-for-the-behavioral-and-health-sciences>. doi:10.4135/9781483329697
- Morrell, J., & Cortina-Borja, M. (2002). The developmental change in strategies parents employ to settle young children to sleep, and their relationship to infant sleeping problems, as assessed by a new questionnaire: The Parental Interactive Bedtime Behaviour Scale. *Infant and Child Development*, 11(1), 17-41.
- Mueller, S., Hemmi, M. H., Wilhelm, F. H., Barr, R. G., & Schneider, S. (2011). Parental report of infant sleep behavior by electronic versus paper-and-pencil diaries, and their relationship to actigraphic sleep measurement. *Journal of Sleep Research*, 20(4), 598-605.
- Nicol, T. (2016). 'Vader-breath' doll a sleeper hit. *NZ Herald*. Retrieved from http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11675932
- Novosad, C., & Thoman, E. B. (2003). The Breathing Bear: An intervention for crying babies and their mothers. *Journal of Developmental and Behavioral Pediatrics*, 24(2), 89-95. doi:10.1097/00004703-200304000-00002
- Palmqvist, H. (1975). The effect of heartbeat sound stimulation on the weight development of newborn infants. *Child Development*, 292-295.
- Plavnick, J. B., & Ferreri, S. J. (2013). Single-case experimental designs in educational research: A methodology for causal analyses in teaching and learning. *Educational Psychology Review*, 25(4), 549-569.

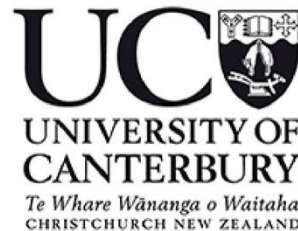
- Rivkees, S. A. (2003). Developing circadian rhythmicity in infants. *Pediatrics*, 112(2), 373-381. doi:10.1542/peds.112.2.373
- Roberts, B., & Campbell, D. (1967). Activity in newborns and the sound of a human heart. *Psychonomic Science*, 9(6), 339-340.
- Roenneberg, T., Kuehnle, T., Juda, M., Kantermann, T., Allebrandt, K., Gordijn, M., & Merrow, M. (2007). Epidemiology of the human circadian clock. *Sleep Medicine Reviews*, 11(6), 429-438.
- Roenneberg, T., Kumar, C. J., & Merrow, M. (2007). The human circadian clock entrains to sun time. *Current Biology*, 17(2), R44.
- Rothbart, M. K. (2007). Temperament, development, and personality. *Current directions in psychological science*, 16(4), 207-212.
- Sadeh, A. (1996). Evaluating night wakings in sleep-disturbed infants: a methodological study of parental reports and actigraphy. *Sleep*, 19, 757-762.
- Sadeh, A. (2004). A brief screening questionnaire for infant sleep problems: validation and findings for an Internet sample. *Pediatrics*, 113(6), e570-e577.
- Sadeh, A. (2011). The role and validity of actigraphy in sleep medicine: an update. *Sleep Medicine Reviews*, 15(4), 259-267.
- Sadeh, A. (2015). III. Sleep assessment methods: Sleep assessment. *Monographs of the Society for Research in Child Development*, 80(1), 33-48. doi:10.1111/mono.12143
- Sadeh, A., Acebo, C., Seifer, R., Aytur, S., & Carskadon, M. A. (1995). Activity-based assessment of sleep-wake patterns during the 1st year of life. *Infant Behavior and Development*, 18(3), 329-337. doi:http://dx.doi.org/10.1016/0163-6383(95)90021-7
- Sadeh, A., & Anders, T. F. (1993). Infant sleep problems: Origins, assessment, interventions. *Infant Mental Health Journal*, 14(1), 17-34. doi:10.1002/1097-0355(199321)14:1<17::AID-IMHJ2280140103>3.0.CO;2-Q
- Sadeh, A., Flint-Ofir, E., Tirosh, T., & Tikotzky, L. (2007). Infant sleep and parental sleep-related cognitions. *Journal of Family Psychology*, 21(1), 74.
- Sadeh, A., Hauri, P. J., Kripke, D. F., & Lavie, P. (1995). The role of actigraphy in the evaluation of sleep disorders. *Sleep*, 18(4), 288-302.
- Sadeh, A., Juda-Hanael, M., Livne-Karp, E., Kahn, M., Tikotzky, L., Anders, T. F., . . . Sivan, Y. (2016). Low parental tolerance for infant crying: an underlying factor in infant sleep problems? *Journal of Sleep Research*, 25(5), 501-507.

- Sadeh, A., & Mindell, J. A. (2016). Infant sleep interventions – Methodological and conceptual issues. *Sleep Medicine Reviews*, 29, 123-125.
doi:<https://doi.org/10.1016/j.smr.2015.11.002>
- Sadeh, A., Tikotzky, L., & Scher, A. (2010). Parenting and infant sleep. *Sleep Medicine Reviews*, 14(2), 89-96. doi:<http://dx.doi.org/10.1016/j.smr.2009.05.003>
- Scher, A. (2005). Infant sleep at 10 months of age as a window to cognitive development. *Early Human Development*, 81(3), 289-292.
doi:<https://doi.org/10.1016/j.earlhumdev.2004.07.005>
- Scher, M. S., Ludington-Hoe, S., Kaffashi, F., Johnson, M. W., Holditch-Davis, D., & Loparo, K. A. (2009). Neurophysiologic assessment of brain maturation after an 8-week trial of skin-to-skin contact on preterm infants. *Clinical Neurophysiology*, 120(10), 1812-1818. doi:10.1016/j.clinph.2009.08.004
- Schmidt, K., Rose, S. A., & Bridger, W. H. (1980). Effect of heartbeat sound on the cardiac and behavioral responsiveness to tactual stimulation in sleeping preterm infants. *Developmental Psychology*, 16(3), 175.
- Schön, R. A., & Silvén, M. (2007). Natural Parenting — Back to Basics in Infant Care. *Evolutionary Psychology*, 5(1), 147470490700500110.
doi:10.1177/147470490700500110
- Serón-Ferré, M., Torres-Farfán, C., Forcelledo, M. L., & Valenzuela, G. J. (2001). The development of circadian rhythms in the fetus and neonate. *Seminars in Perinatology*, 25(6), 363-370. doi:10.1053/sper.2001.29037
- Shinohara, H., & Kodama, H. (2011). Relationship between circadian salivary melatonin levels and sleep-wake behavior in infants. *Pediatrics International*, 53(1), 29-35.
doi:10.1111/j.1442-200X.2010.03186.x
- Sitnick, S. L., Goodlin-Jones, B. L., & Anders, T. F. (2008). The use of actigraphy to study sleep disorders in preschoolers: some concerns about detection of nighttime awakenings. *Sleep*, 31(3), 395.
- So, K., Buckley, P., Adamson, T. M., & Horne, R. S. (2005). Actigraphy correctly predicts sleep behavior in infants who are younger than six months, when compared with polysomnography. *Pediatric Research*, 58(4), 761-765.
- So, K., Michael Adamson, T., & Horne, R. S. (2007). The use of actigraphy for assessment of the development of sleep/wake patterns in infants during the first 12 months of life. *Journal of Sleep Research*, 16(2), 181-187.
- Spencer, J. A., Moran, D. J., Lee, A., & Talbert, D. (1990). White noise and sleep induction. *Archives of Disease in Childhood*, 65(1), 135-137. doi:10.1136/adc.65.1.135
- Spruyt, K., Aitken, R. J., So, K., Charlton, M., Adamson, T. M., & Horne, R. S. C. (2008). Relationship between sleep/wake patterns, temperament and overall development in

- term infants over the first year of life. *Early Human Development*, 84(5), 289-296.
doi:10.1016/j.earlhumdev.2007.07.002
- St James-Roberts, I., Roberts, M., Hovish, K., & Owen, C. (2017). Video evidence that parenting methods predict which infants develop long night-time sleep periods by three months of age. *Primary Health Care Research & Development*, 18(3), 212.
doi:10.1017/S1463423616000451
- Thoman, E. B. (1990). Sleeping and waking states in infants: A functional perspective. *Neuroscience & Biobehavioral Reviews*, 14(1), 93-107.
doi:http://dx.doi.org/10.1016/S0149-7634(05)80165-4
- Thoman, E. B., & Graham, S. E. (1986). Self-regulation of stimulation by premature infants. *Pediatrics*, 78(5), 855.
- Thoman, E. B., Hammond, K., Affleck, G., & Desilva, H. N. (1995). The breathing bear with preterm infants: Effects on sleep, respiration, and affect. *Infant Mental Health Journal*, 16(3), 160-168. doi:10.1002/1097-0355(199523)16:3<160::AID-IMHJ2280160302>3.0.CO;2-V
- Thoman, E. B., Ingersoll, E. W., & Acebo, C. (1991). Premature infants seek rhythmic stimulation, and the experience facilitates neurobehavioral development. *Journal of developmental and behavioral pediatrics : JDBP*, 12(1), 11-18.
doi:10.1097/00004703-199102000-00004
- Thomas, A., & Chess, S. (1977). *Temperament and development*. Oxford, England: Brunner/Mazel.
- Thomas, K. A., Burr, R. L., Spieker, S., Lee, J., & Chen, J. (2014). Mother-infant circadian rhythm: Development of individual patterns and dyadic synchrony. *Early Human Development*, 90(12), 885-890. doi:10.1016/j.earlhumdev.2014.09.005
- Tikotzky, L., & Sadeh, A. (2009). Maternal sleep-related cognitions and infant sleep: A longitudinal study from pregnancy through the 1st Year. *Child Development*, 80(3), 860-874.
- Touchette, E., Petit, D., Paquet, J., Boivin, M., Japel, C., Tremblay, R. E., & Montplaisir, J. Y. (2005). Factors associated with fragmented sleep at night across early childhood. *Archives of Pediatrics and Adolescent Medicine*, 159(3), 242.
- Tulloch, J. D., Brown, B. S., Jacobs, H. L., Prugh, D. G., & Greene, W. A. (1964). Normal Heartbeat Sound and the Behavior of Newborn Infants--A Replication Study. *Psychosomatic Medicine*, 26(6), 661-670.
- Vannest, K. J., & Ninci, J. (2015). Evaluating Intervention Effects in Single-Case Research Designs. *Journal of Counseling & Development*, 93(4), 403-411.
doi:10.1002/jcad.12038

- Weinraub, M., Bender, R. H., Friedman, S. L., Susman, E. J., Knoke, B., Bradley, R., . . . Williams, J. (2012). Patterns of developmental change in infants' nighttime sleep awakenings from 6 through 36 months of age. *Developmental Psychology*, 48(6), 1511-1528. doi:10.1037/a0027680
- Zaidman-Zait, A., & Hall, W. A. (2015). Children's night waking among toddlers: relationships with mothers' and fathers' parenting approaches and children's behavioural difficulties. *Journal of Advanced Nursing*, 71(7), 1639-1649. doi:10.1111/jan.12636

Appendix A: Recruitment Poster



CALLING RESEARCH PARTICIPANTS

Are you planning to use a Lulla Doll?

My name is Hannah and I am a Masters student at the University of Canterbury investigating the effects of the Lulla Doll on infant sleep.

For my project I am looking for families in the Christchurch area with infants between 4 and 8 months of age who are interested in trialling a Lulla Doll but have not yet done so.

I am looking for infants who currently fall asleep in their cot but may have difficulty with settling to sleep or night wakings.

Parents will receive \$50.00 for their participation on completion of the project.

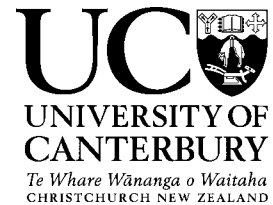
A limited number of dolls are available for loan for the duration of the study. An opportunity to purchase the doll will be made available upon conclusion of the study.

For more information, contact Hannah on 027 325 6184 or at hannah.oloughlin@pg.canterbury.ac.nz

Eligibility criteria applies.

Appendix B: Information Sheet

Hannah O'Loughlin
 School of Health Sciences
 Telephone: +64 27 325 6184
 Email: Hannah.oloughlin@pg.canterbury.ac.nz



14 November 2016

The Effects of a Breathing, Heartbeating (Lulla Doll) on Infant Sleep Information Sheet for Parents and Caregivers

My name is Hannah O'Loughlin and I am a Masters student in the Child and Family Psychology programme at the University of Canterbury. The aim of my research is to investigate the effects the Lulla Doll by RoRo has on infant sleep. I am also interested in the experiences of parents who choose to purchase and use a Lulla Doll. In order to do so, I am recruiting families who have purchased but not used or are planning to purchase a Lulla Doll, to help us investigate the effects of the Lulla Doll on infant sleep and share their experiences.

If you choose to take part in this study, your involvement in this project will include sharing your experiences with your child's sleep, what led you to purchasing a Lulla Doll, sharing your experience of the Lulla Doll and providing information about your child's sleep before using the Lulla Doll and during use of the Lulla Doll. This will be achieved by the following method:

Interview 1:

An initial 30-minute interview will be conducted to hear about your child's sleep, your interest in the Lulla Doll, and to set up the video equipment. This interview will be audio-recorded to aid the researcher to accurately recall your comments. You will have an opportunity to check or clarify the information you have given.

Sleep Diaries:

Parents will be requested to complete sleep diaries for 5, 10 or 15 days before the introduction of the Lulla Doll, and for 3 weeks during use of the Lulla Doll and again for one week one month later. The sleep diaries will record your infant's day and night sleep and other details such as number of wakings, duration of wakings and your response to wakings.

Sleep Recordings;

Videosomnography of your child's sleep will be collected at several different points throughout the project. Video footage will be collected before the introduction of the Lulla Doll and also after the introduction of the Lulla Doll. There will be 9-15 nights total

of video footage collected throughout the course of the study. Videosomnography is a low illumination camera which will record what happens during the night in your infant's cot. Only the child, his or her bed and possibly your hands will be visible, but background noise will be able to be heard. This is a well-established sleep research procedure and all you will need to do is help us plan where to safely position the equipment. I will set up the equipment and programme it to start and finish at set times and then return to collect it. It will not require anyone entering your home at night.

Interview 2:

A 15 minute follow up interview will be conducted after the use of the Lulla Doll to hear about your experiences with the Lulla Doll and your child's sleep. This interview will also be audio-recorded to aid the researcher to accurately recall your comments. You will have an opportunity to check or clarify the information you have given.

Summary of your participation:

- One 30 minute and one 15 minute interviews with the researcher
- 9-15 nights of videosomnography of your infant's sleep over the course of the project
- Sleep diaries to be completed for either 5,10 or 15 days prior to introducing the Lulla Doll to your infant, followed by a further 3 weeks of sleep diaries following initial introduction of the doll to your infant and then an additional 1 week of diaries, 4 weeks after the initial 3 weeks of diaries.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you and it will not be included in the study.

In recognition of the time required of participants to participate in the project, parents will receive \$50.00. This will be provided to parents who have participated for the duration of the study and have completed the questionnaire and sleep diaries in addition to video footage. This will be given to the parents on completion of their involvement in the project.

A limited number of dolls will be able for loan. Lulla Dolls that are on loan will be provided to the family for use for the duration of the study. Upon completion of the study the family will be offered to return the doll to the researcher or to purchase the doll from the researcher. The dolls will be sold to the families at retail value of \$110.00. Families may choose to use the \$50.00 participation fund as part payment of the doll.

All information you provide to the researcher will be confidential, unless Dr. Karyn France or I have concerns about anyone's safety. In this situation, we would discuss these concerns with you, if possible, before deciding what action to take. Any information or data gathered for the project will be kept securely in locked filing cabinets and on password protected computers. Coded identifiers will be used in place of names to ensure your anonymity on any raw data. This data will be stored away from your personal

information to ensure your anonymity. This information will be destroyed five years after the project is completed.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation. To ensure anonymity and confidentiality any identifiers will be coded and pseudonyms used for individual children. A thesis is a public document and will be available through the UC Library. Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement of Master of Arts degree by Hannah O'Loughlin under the supervision of Dr Karyn France who can be contacted at karyn.france@canterbury.ac.nz. She will be pleased to discuss any concerns you may have about participation in the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, please contact the researcher by email or phone. Participant positions will be filled in order of contact with the researcher. If you understand and agree to take part in this study, please complete the following consent form. This will be collected from you by the researcher prior to the first initial interview.

Kind Regards,

Hannah O'Loughlin

Dr Karyn France
Registered Clinical Psychologist,
Co-ordinator Child and Family Psychology Programme
University of Canterbury
Private Bag 4800.
Christchurch, New Zealand
Ph (03) 364261- Fax (03) 364241

Contact Numbers:

Hannah: 027 325 6184
Plunket Line: 0800 933 922
Healthline: 0800 611 116

Appendix C: Ethics Approval Letters



HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
 Telephone: +64 03 364 2987, Extn 45588
 Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/101

21 October 2016

Hannah O'Loughlin
 School of Health Sciences
 UNIVERSITY OF CANTERBURY

Dear Hannah

The Human Ethics Committee advises that your research proposal "The Effects on Infant Sleep of a Breathing, Heartbeating (Lulla) Doll" has been considered and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your emails of 21st September and 18th October 2016.

Best wishes for your project.

Yours sincerely

R. Robinson
 pp.

Kelly Dombroski
Chair
University of Canterbury Human Ethics Committee



HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 369 4588, Extn 94588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/101 Amendment 1

23 November 2016

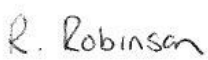
Hannah O'Loughlin
School of Health Sciences
UNIVERSITY OF CANTERBURY

Dear Hannah

Thank you for your request for an amendment to your research proposal "The Effects on Infant Sleep of a Breathing, Heartbeating (Lulla) Doll" as outlined in your email dated 18th November 2016.

I am pleased to advise that this request has been considered and approved by the Human Ethics Committee.

Yours sincerely

pp. 

Jane Maidment
Chair, Human Ethics Committee



HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
 Telephone: +64 03 369 4588, Extn 94588
 Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/101 Amendment 2

20 December 2016

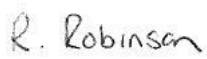
Hannah O'Loughlin
 School of Health Sciences
 UNIVERSITY OF CANTERBURY

Dear Hannah

Thank you for your request for an amendment to your research proposal "The Effects on Infant Sleep of a Breathing, Heartbeating (Lulla) Doll" as outlined in your email dated 12th December 2016.

I am pleased to advise that this request has been considered and approved by the Human Ethics Committee.

Yours sincerely

pp. 

Associate Professor Jane Maidment
Chair, Human Ethics Committee

Appendix D: Consent forms for participants

Hannah O'Loughlin
 School of Health Sciences
 Telephone: +64 27 325 6184
 Email: Hannah.oloughlin@pg.canterbury.ac.nz



The Effects of a Breathing, Heartbeating (Lulla Doll) on Infant Sleep Consent Form for Parents and Caregivers.

Please tick the following boxes to give your consent

- ☐ I have been given a full explanation of this project and have had the opportunity to ask questions.
- ☐ I understand what is required of me if I agree to take part in the research.
- ☐ I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.
- ☐ I understand that any information or opinions I provide will be kept confidential to the researcher, her supervisors and a research assistant unless Dr. Karyn France or the researcher has concerns about anyone's safety. In this situation, these concerns would be discussed with us, if possible, before a decision about what action to take, is made.
- ☐ I understand that to receive the \$50.00 compensation I must complete the interviews, sleep diaries and video footage.
- ☐ I understand that the \$50.00 compensation will be provided at the end of the study.
- ☐ I understand that I have been loaned the loan Lulla Doll for the duration of the study only.
- ☐ I understand that I will have the opportunity to purchase the Lulla Doll upon the completion of the study for a price of \$110.00.
- ☐ I understand that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through the UC Library.
- ☐ I understand that all data collected for the study will be kept in locked and secure facilities and in password protected electronic form and will be destroyed after five years.
- ☐ I understand that I can contact the researcher Hannah O'Loughlin or her supervisor Dr. Karyn France for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)
- ☐ I would like a summary of the results of the project and have provided an email address below.
- ☐ By signing below, I am declaring that I have read and understood the statements above and agree to participate in this study.

Name:			
Signature:		Date:	
Email address: (for summary of results)			

Hannah O'Loughlin
 School of Health Sciences
 Telephone: +64 27 325 6184
 Email: Hannah.oloughlin@pg.canterbury.ac.nz



The Effects of a Breathing, Heartbeating (Lulla Doll) on Infant Sleep Consent Form for Parents and Caregivers.

Please tick the following boxes to give your consent

- ☐ I have been given a full explanation of this project and have had the opportunity to ask questions.
- ☐ I understand what is required of me if I agree to take part in the research.
- ☐ I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.
- ☐ I understand that any information or opinions I provide will be kept confidential to the researcher, her supervisors and a research assistant unless Dr. Karyn France or the researcher has concerns about anyone's safety. In this situation, these concerns would be discussed with us, if possible, before a decision about what action to take, is made.
- ☐ I understand that to receive the \$50.00 compensation I must complete the interviews, sleep diaries and video footage.
- ☐ I understand that the \$50.00 compensation will be provided at the end of the study.
- ☐ I understand that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through the UC Library.
- ☐ I understand that all data collected for the study will be kept in locked and secure facilities and in password protected electronic form and will be destroyed after five years.
- ☐ I understand that I can contact the researcher Hannah O'Loughlin or her supervisor Dr. Karyn France for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)
- ☐ I would like a summary of the results of the project and have provided an email address below.
- ☐ By signing below, I am declaring that I have read and understood the statements above and agree to participate in this study.

Name:	
Signature:	
Date:	
Email address (<i>for report of findings, if applicable</i>):	

Appendix E: Sleep Diary

NAME:

Date							
------	--	--	--	--	--	--	--

Time down							
Time awake							
Where							
Time down							
Time awake							
Where							

Key:

Night Sleep

Where							
Bedtime/ comment							
Time from in bed to silence + Nature of sounds& mins							
What did you do							
Night Wakings: Please note down:- time awake - approx duration - what did child do? - what did you do?	#1						
	#2						
	#3						
	#4						
	#5						
	#6						
	#7						
Time up for the day							

Child Response Key:

Comments:

Parent Response Key: